

US3242288 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:10:30

All time stamps listed in this document are displayed in GMT

US3242288

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Participant ID

US3242288

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

US3242288

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

US3242288

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Date of Informed Consent (*dd MMM yyyy*) 3 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3242288

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Did the participant meet all eligibility criteria?

Yes ☒
No ☐

US3242288

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Were any significant conditions reported?

Yes ☒
No ☐

US3242288

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242288

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3242288

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242288

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242288

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Condition	BRADYCARDIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242288

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Condition	HYPERPLASIA BILATERAL BREAST
Start date (dd MMM yyyy)	UN AUG 2020
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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242288

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	09:11 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:11
Height (xxx.x)	67 in
Weight (xxx.x)	209 lb
BMI (xxx.x)	32.80247 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242288

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Date of assessment (dd MMM yyyy) 3 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2016

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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) 12 Feb 2021 18:28:40

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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	

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

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

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

Folder OID	VISIT1
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US3242288

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

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

What was the participant's randomization number? 111110

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) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Height	ND - Not Done
Weight	ND - Not Done

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:22
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:00
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3242288

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

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.

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 03 SEP 2020

What was the treatment time? (00:00-23:59) 10:29 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 10:29

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

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 3 SEP 2020

Collection time (00:00-23:59) 10:17 (24 HR)

Collection date and time (derived) 3 SEP 2020 10:17

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:15	3 SEP 2020 10:15
Nasopharyngeal Swab 2	No		

US3242288

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 11:02

PC Open Date & Time

03 SEP 2020 10:49

PC Close Date & Time

03 SEP 2020 13:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:40

PC Open Date & Time

03 SEP 2020 14:14

PC Close Date & Time

04 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

09 SEP 2020 12:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 11:02

PC Open Date & Time

03 SEP 2020 10:49

PC Close Date & Time

03 SEP 2020 13:19

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:40

PC Open Date & Time

03 SEP 2020 14:14

PC Close Date & Time

04 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 16:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 11:02
PC Open Date & Time	03 SEP 2020 10:49
PC Close Date & Time	03 SEP 2020 13:19

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:40
PC Open Date & Time	03 SEP 2020 14:14
PC Close Date & Time	04 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

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 ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:22
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

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 ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

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 ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:55
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

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 ☒

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EAB) (1725)

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:05
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

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 ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:30
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:15
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

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 VISIT2

US3242288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
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	

US3242288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

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.

US3242288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Confirmed COVID-19 <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	_____
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
<hr/>	
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____

US3242288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3242288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:10:30

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3242288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

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

Visit date (dd MMM yyyy)	5 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 15:58
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

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.

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 5 NOV 2020

Collection time (00:00-23:59) 16:28 (24 HR)

Collection date and time (derived) 5 NOV 2020 16:28

US3242288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:41

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	05 NOV 2020 16:05:51
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	11 NOV 2020 10:29:11
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 NOV 2020 11:35:06
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 NOV 2020 09:33:26
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 13:50:54
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 12:07:49
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 08:13:59

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

22 DEC 2020 17:03:33

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 DEC 2020 08:41:02
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 JAN 2021 14:49:30
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 JAN 2021 09:18:53
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 09:38:08

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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	27 JAN 2021 15:10:22
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	30 JAN 2021 11:17:32
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 <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	06 FEB 2021 00:17:07
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 FEB 2021 10:41:09
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 10:06:40

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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	27 FEB 2021 10:21:30
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 MAR 2021 00:09:17
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 00:01:38

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 MAR 2021 11:10:12
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 MAR 2021 18:13:36

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 09:08:49

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 09:54:59

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 09:37:02

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 APR 2021 10:03:50
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 <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 MAY 2021 12:02:33
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3242288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:10:30

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
Yes	No	27 FEB 2021 10:21:50

US3242288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 14:45:29

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 14:45:29

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 19:59:01

Generated On: 11 Aug 2021 22:10:30

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

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:59:01

Generated On: 11 Aug 2021 22:10:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3242288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 19:59:01

Generated On: 11 Aug 2021 22:10:30

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.

US3242288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 19:59:01

Generated On: 11 Aug 2021 22:10:30

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 30 MAR 2021

Collection time (00:00-23:59) 16:34 (24 HR)

Collection date and time (derived) 30 MAR 2021 16:34

US3242288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:59:01

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Date of Contact	11 SEP 2020
Time of Contact	09:12
Date and Time of Contact (derived)	11 SEP 2020 09:12
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

Symptom Day

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 (1)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

Symptom Day

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

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Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 11 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

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Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.6 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"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 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 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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

Temperature	99.8 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 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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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 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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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 11 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

	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"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Date of Visit	11 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	11 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

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

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US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 SEP 2020
Day 5	Yes	15 SEP 2020
Day 7	Yes	17 SEP 2020
Day 9	Yes	19 SEP 2020
Day 14	Yes	25 SEP 2020
Day 21	Yes	02 OCT 2020
Day 28	Yes	8 OCT 2020

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

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

Visit date (dd MMM yyyy)	11 SEP 2020
--------------------------	-------------

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

Folder OID	SICKD1
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US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:20
Height (xxx.x)	67 in
Weight (xxx.x)	209 lb
Temperature (xxx.x)	99.6 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3242288

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 SEP 2020

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SICKD28

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	07:59 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 07:59
Height (xxx.x)	67 in
Weight (xxx.x)	209 lb
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3242288

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 OCT 2020

US3242288

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 07 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242288

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 16:08:34

Generated On: 11 Aug 2021 22:10:30

Date of updated informed consent (<i>dd MMM yyyy</i>)	07 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>)	07 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3242288

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Height	67 in
Weight	209 lb
BMI (xxx.x)	32.80247

US3242288

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Height	67 in
Weight	209 lb
BMI (xxx.x)	32.80247
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)	7 JAN 2021
Time of assessment (00:00-23:59)	16:58 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 16:58
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3242288

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Height	67 in
Weight	209 lb
BMI (xxx.x)	32.80247
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)	7 JAN 2021
Time of assessment (00:00-23:59)	17:57 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 17:57
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3242288

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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.

US3242288

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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) 7 JAN 2021

What was the treatment time? (00:00-23:59) 17:26 (24 HR)

Treatment Date and Time (derived) 7 JAN 2021 17:26

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

US3242288

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 JAN 2021

Collection time (00:00-23:59)

16:42 (24 HR)

Collection date and time (derived)

07 JAN 2021 16:42

US3242288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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

Collection date (dd MMM yyyy)	07 JAN 2021
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Collection time (00:00 - 23:59)	16:41
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Collection Date and Time (derived)	07 JAN 2021 16:41
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US3242288

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3242288

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

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.

US3242288

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 1 FEB 2021

Collection time (00:00-23:59) 16:30 (24 HR)

Collection date and time (derived) 1 FEB 2021 16:30

US3242288

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

AEID	USA-US067-2020-MRNA-1273-P30 1000004
Adverse event	SAR-COV-2
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	09 SEP 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)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

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

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

AEID

Adverse event

WORSENING HYPERLIPIDEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:22:39

Generated On: 11 Aug 2021 22:10:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 0.1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication ARIMIDEX

Prophylaxis Yes ☐
No ☒

Indication HYPERPLASIA IN BREAST
TISSUE, BILATERAL

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER(COVID-19 SYMPTOMS)

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication DAYQUIL(ACETAMINOPHEN
325 MG DEXTROMETHORPHAN
HBR 10 MG
PHENYLEPHRINE HCL 5 MG)

Prophylaxis Yes ☐
No ☒

Indication FEVER AND CONGESTION
(COVID-19 SYMPTOMS)

Dose per administration 2

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

If dose unit is Other, specify CAPSULES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication SHRINGRIX

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR SHINGLES

Dose per administration 0.50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication RED YEAST RICE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT FOR
HYPERLIPIDEMIA

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

Name of Medication BOTOX

Prophylaxis Yes ☒
No ☐

Indication COSMETIC

Dose per administration 64

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:18:14

Generated On: 11 Aug 2021 22:10:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2014		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3242288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:27:31

Generated On: 11 Aug 2021 22:10:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Feb 2021 18:27:33

Generated On: 11 Aug 2021 22:10:30

Date of dosing discontinuation (dd MMM yyyy) 14 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

US3242288

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:10:30

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 ☐

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 11:31
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

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 13:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/SEP/2020 11:37
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

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 18:28:40

Generated On: 11 Aug 2021 22:10:30

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/SEP/2020 12:49
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

US3242288 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242288

Form: Participant Creation

Generated On: 11 Aug 2021 22:10:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:29:23
User entered 'US3242288'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:35:10

US3242288

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:17

US3242288

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:30:53
User entered '03 SEP 2020'	RWS_ENDPOINT	03 Sep 2020 13:35:11
	ENDPOINT (b) (4)	

US3242288

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:30:53
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:17

US3242288

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'SCRN'	(b) (4), (b) (6) System	03 Sep 2020 13:58:17

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered (b) (6) 1962'	RWS_ENDPOINT	03 Sep 2020 13:35:12
	ENDPOINT (b) (4)	

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '58'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
User entered 'YEARS'	(b) (4), (b) (6) System	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
User entered '58'	(b) (4), (b) (6) System	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered 'Female (F)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered 'I'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:30

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Sep 2020'	(b) (4), (b) (6) System	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2020'	(b) (4), (b) (6) System	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered empty.	RWS_ENDPOINT	03 Sep 2020 13:35:11
	ENDPOINT (b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'I'	(b) (4), (b) (6) System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:17:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:51

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Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:10:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:07
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:37

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:24:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:24:49
Data point term sent to Coder	System	03 Sep 2020 14:24:16
User entered 'Hypertension'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2000'	(b) (4), (b) (6) System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2000'	(b) (4), (b) (6) System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:24:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:24:49
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 14:24:16
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2005'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2005'	(b) (4), (b) (6) System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2005'	(b) (4), (b) (6) System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:24:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:24:49
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 14:24:18
User entered 'Obesity'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2015'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2015'	(b) (4), (b) (6) System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2015'	(b) (4), (b) (6) System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:26:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:26:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 14:25:20
User entered 'Postmenopausal'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2016'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2016'	(b) (4), (b) (6) System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2016'	(b) (4), (b) (6) System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:26:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:26:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 14:25:18
User entered 'Bradycardia'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Un UNK 2010'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2010'	(b) (4), (b) (6) System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2010'	(b) (4), (b) (6) System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:27:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:27:49
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 14:26:21
User entered 'Gastric Sleeve'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2017'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2017'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2017'	(b) (4), (b) (6) System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2017'	(b) (4), (b) (6) System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Jan 2017'	(b) (4), (b) (6) System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2017'	(b) (4), (b) (6) System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Breast hyperplasia, LLT: Bilateral mammary hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 18:38:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 18:38:43
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 16:31:18
User entered 'Hyperplasia bilateral breast'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN Aug 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'Aug 2020'	(b) (4), (b) (6) System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '2020'	(b) (4), (b) (6) System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 14:26:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 14:26:08
User entered '09:11' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Sep 2020 14:26:08
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 14:25:59
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User entered '3 Sep 2020 09:11'	System	03 Sep 2020 14:26:08
User entered empty.	System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered '67' in	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered '209' lb	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User entered '32.80247'	System	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'bpm'	(b) (4), (b) (6) System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'breaths/min'	(b) (4), (b) (6) System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'mmHg'	(b) (4), (b) (6) System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'mmHg'	(b) (4), (b) (6) System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	

US3242288

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:19

US3242288

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:56
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.'	(b) (4), (b) (6)	23 Sep 2020 17:01:35
canceled (Site from System).		
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 19:18:31
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:19

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered 'UN UNK 2016'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:10:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:43:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[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 21:08:48
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[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 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'I'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:41
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Nov 2020 12:42:13
User entered '03 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:29
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:29
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'VISIT1'	(b) (4), (b) (6) System	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered '03 SEP 2020'	RWS_ENDPOINT	03 Sep 2020 14:20:06
	ENDPOINT (b) (4)	

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered '111110'	RWS_ENDPOINT	03 Sep 2020 14:20:06
	ENDPOINT (b) (4)	

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:20:06

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Sep 2020 13:04:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:07:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:06:41

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '09:22'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '3 Sep 2020 09:22'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '98.5' F	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '56'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'bpm'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '12'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'breaths/min'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '124'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'mmHg'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '78'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'mmHg'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '11:00'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '3 Sep 2020 11:00'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '97.4' F	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '56'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'bpm'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '16'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'breaths/min'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '124'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'mmHg'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '80'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'mmHg'	(b) (4), (b) (6) System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:25
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:59

US3242288

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:25
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:30:59

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User closed query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:25:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:34:44
Query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	09 Nov 2020 14:34:33
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:34:26
User entered '03 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:34:26
User opened query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:05:19
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered '10:29'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User entered '03 Sep 2020 10:29'	System	09 Nov 2020 14:34:26
User entered '3 Sep 2020 10:29'	System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered 'ONCE'	System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:42
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:42
User entered '10:17'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '3 Sep 2020 10:17'	(b) (4), (b) (6) System	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered '10:15'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '3 Sep 2020 10:15'	(b) (4), (b) (6) System	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered empty.	(b) (4), (b) (6) System	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:59
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:04

US3242288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '1'	(b) (4), (b) (6) System	03 Sep 2020 14:31:04

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:01:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	(b) (4), (b) (6) System	03 Sep 2020 15:02:08
User entered 'Yes (Y)'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:01:54', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570' User entered '97.4'	(b) (4), (b) (6) System	03 Sep 2020 15:02:08
	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:01:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	(b) (4), (b) (6)	
User entered 'No (N)'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:02', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	(b) (4), (b) (6) System	03 Sep 2020 15:02:08
User entered '03 Sep 2020 11:02'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '03 Sep 2020 10:49'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '03 Sep 2020 13:19'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:39:50', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	(b) (4), (b) (6) System	04 Sep 2020 01:40:09
User entered 'Yes (Y)'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:39:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	(b) (4), (b) (6)	
User entered '98.4'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	(b) (4), (b) (6) System	04 Sep 2020 01:40:09
User entered 'No (N)'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	(b) (4), (b) (6) System	04 Sep 2020 01:40:09
User entered '03 Sep 2020 21:40'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '03 Sep 2020 14:14'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 2'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:25', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	(b) (4), (b) (6)	
User entered '98.2'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:34', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	(b) (4), (b) (6) System	04 Sep 2020 16:21:42
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 3'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:07', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:12', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	(b) (4), (b) (6)	
User entered '98.3'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:15', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	(b) (4), (b) (6) System	05 Sep 2020 16:01:56
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 4'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:47', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	(b) (4), (b) (6) System	06 Sep 2020 20:55:05
User entered 'Yes (Y)'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:53', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	(b) (4), (b) (6)	
User entered '98.3'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:56', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	(b) (4), (b) (6)	
	System	06 Sep 2020 20:55:05
User entered 'No (N)'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	(b) (4), (b) (6) System	06 Sep 2020 20:55:05
User entered '06 Sep 2020 16:54'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 5'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	(b) (4), (b) (6) System	07 Sep 2020 16:05:19
User entered 'Yes (Y)'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	(b) (4), (b) (6)	
User entered '98.6'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:12', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:15', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	(b) (4), (b) (6) System	07 Sep 2020 16:05:19
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 6'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:22', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	(b) (4), (b) (6)	
User entered '98.5'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:32', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	(b) (4), (b) (6) System	08 Sep 2020 16:29:39
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 7'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6' User entered '97.9'	(b) (4), (b) (6) System	09 Sep 2020 16:15:20
	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:13', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:16', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	(b) (4), (b) (6) System	09 Sep 2020 16:15:20
User entered '09 Sep 2020 12:15'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	(b) (4), (b) (6) System	03 Sep 2020 15:02:25
User entered 'None (1)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:14', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	(b) (4), (b) (6) System	03 Sep 2020 15:02:25
User entered 'No (N)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:17', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	(b) (4), (b) (6) System	03 Sep 2020 15:02:25
User entered 'No (N)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:20', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	(b) (4), (b) (6) System	03 Sep 2020 15:02:25
User entered 'None (1)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	(b) (4), (b) (6) System	03 Sep 2020 15:02:25
User entered '03 Sep 2020 11:02'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '03 Sep 2020 10:49'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '03 Sep 2020 13:19'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:09', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	(b) (4), (b) (6)	
	System	04 Sep 2020 01:40:31
User entered 'None (1)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:18', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	(b) (4), (b) (6)	
	System	04 Sep 2020 01:40:31
User entered 'No (N)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:21', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	(b) (4), (b) (6) System	04 Sep 2020 01:40:31
User entered 'No (N)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:24', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	(b) (4), (b) (6)	
	System	04 Sep 2020 01:40:31
User entered 'None (1)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:27', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	(b) (4), (b) (6) System	04 Sep 2020 01:40:31
User entered '03 Sep 2020 21:40'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '03 Sep 2020 14:14'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 2'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	(b) (4), (b) (6)	
	System	04 Sep 2020 16:22:02
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:52', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:56', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	(b) (4), (b) (6)	
	System	04 Sep 2020 16:22:02
User entered 'None (1)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	(b) (4), (b) (6) System	04 Sep 2020 16:22:02
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 3'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:26', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	(b) (4), (b) (6) System	05 Sep 2020 16:02:35
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	(b) (4), (b) (6) System	05 Sep 2020 16:02:35
User entered 'No (N)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	(b) (4), (b) (6) System	05 Sep 2020 16:02:35
User entered 'No (N)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:36', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	(b) (4), (b) (6) System	05 Sep 2020 16:02:35
User entered 'None (1)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:38', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	(b) (4), (b) (6) System	05 Sep 2020 16:02:35
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 4'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	(b) (4), (b) (6) System	06 Sep 2020 20:55:16
User entered 'None (1)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:06', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	(b) (4), (b) (6) System	06 Sep 2020 20:55:16
User entered 'No (N)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	(b) (4), (b) (6) System	06 Sep 2020 20:55:16
User entered 'No (N)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:11', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	(b) (4), (b) (6)	
	System	06 Sep 2020 20:55:16
User entered 'None (1)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:13', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	(b) (4), (b) (6) System	06 Sep 2020 20:55:16
User entered '06 Sep 2020 16:55'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 5'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	(b) (4), (b) (6)	
	System	07 Sep 2020 16:05:33
User entered 'None (1)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	(b) (4), (b) (6) System	07 Sep 2020 16:05:33
User entered 'No (N)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:26', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	(b) (4), (b) (6) System	07 Sep 2020 16:05:33
User entered 'No (N)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:28', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	(b) (4), (b) (6)	
	System	07 Sep 2020 16:05:33
User entered 'None (1)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:30', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	(b) (4), (b) (6) System	07 Sep 2020 16:05:33
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 6'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	(b) (4), (b) (6)	
	System	08 Sep 2020 16:29:54
User entered 'None (1)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:41', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:43', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:48', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	(b) (4), (b) (6) System	08 Sep 2020 16:29:54
User entered 'None (1)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	(b) (4), (b) (6) System	08 Sep 2020 16:29:54
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 7'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	(b) (4), (b) (6)	
	System	09 Sep 2020 16:15:31
User entered 'None (1)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:22', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:24', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	(b) (4), (b) (6) System	09 Sep 2020 16:15:31
User entered 'No (N)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

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 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:27', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	(b) (4), (b) (6)	
	System	09 Sep 2020 16:15:31
User entered 'None (1)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	(b) (4), (b) (6) System	09 Sep 2020 16:15:31
User entered '09 Sep 2020 12:15'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:28', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:30', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6)	
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:33', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered 'No (N)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	(b) (4), (b) (6) System	03 Sep 2020 15:02:52
User entered '03 Sep 2020 11:02'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '03 Sep 2020 10:49'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '03 Sep 2020 13:19'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6) System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:33', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6) System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6) System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6) System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:41', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6) System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6)	
	System	04 Sep 2020 01:40:56
User entered 'No (N)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	(b) (4), (b) (6) System	04 Sep 2020 01:40:56
User entered '03 Sep 2020 21:40'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '03 Sep 2020 14:14'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 2'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:07', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6) System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:12', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:14', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:17', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	(b) (4), (b) (6) System	04 Sep 2020 16:22:20
User entered '04 Sep 2020 12:22'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 3'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:44', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:48', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:50', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:54', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered 'No (N)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:56', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	(b) (4), (b) (6) System	05 Sep 2020 16:03:00
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 4'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:17', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 20:55:35
	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:21', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 20:55:35
	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 20:55:35
	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:25', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 20:55:35
	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:27', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 20:55:35
	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	(b) (4), (b) (6) System	06 Sep 2020 20:55:35
User entered '06 Sep 2020 16:55'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 5'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:44', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	(b) (4), (b) (6) System	07 Sep 2020 16:05:56
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 6'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:55', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:01', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered 'No (N)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	(b) (4), (b) (6) System	08 Sep 2020 16:30:13
User entered '08 Sep 2020 12:30'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 7'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:32', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:34', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6) System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:36', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6)	
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6) System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6) System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:41', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6) System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

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 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:43', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:45', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	(b) (4), (b) (6) System	09 Sep 2020 16:15:50
User entered '09 Sep 2020 12:15'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:20
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered 'Yes (Y)'	Grace Newville (b) (4)	11 Sep 2020 13:35:18
	(b) (4)	

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered '11 Sep 2020'	Grace Newville (b) (4)	11 Sep 2020 13:35:18
	(b) (4)	

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	11 Sep 2020 13:35:18
	(b) (4)	

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered empty.	Grace Newville (b) (4)	11 Sep 2020 13:35:18
	(b) (4)	

US3242288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:48
User entered 'Yes (Y)'	Grace Newville (b) (4)	11 Sep 2020 13:36:05
	(b) (4)	

US3242288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '1'	(b) (4), (b) (6) System	11 Sep 2020 13:36:05

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Sep 2020 15:28:22
	(b) (4)	

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:04
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Dec 2020 00:03:28
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Dec 2020 00:03:28
User entered '18 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	18 Dec 2020 00:03:28
	(b) (4)	
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Dec 2020 00:02:57
DataPoint Un-verified.	Erynn McKinley (b) (4)	18 Dec 2020 00:02:57
	(b) (4)	
User entered '21 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	18 Dec 2020 00:02:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered '18 Sep 2020'	Grace Newville (b) (4)	21 Sep 2020 15:28:22
	(b) (4)	

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	21 Sep 2020 15:28:22
	(b) (4)	

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered empty.	Grace Newville (b) (4)	21 Sep 2020 15:28:22
	(b) (4)	

US3242288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:09
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Sep 2020 15:28:26
	(b) (4)	

US3242288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:46:50
User entered '1'	(b) (4), (b) (6) System	21 Sep 2020 15:28:26

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:33
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:33
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:33
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:33
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:33
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:10:21

US3242288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:33
User entered '1'	(b) (4), (b) (6) System	25 Sep 2020 17:10:21

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:36
User closed query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 21:53:24
User opened query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 21:53:09
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:53:09
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:50:57
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Nov 2020 21:53:31
User entered empty; reason for change Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:53:31
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Nov 2020 21:53:24
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	05 Nov 2020 21:53:24
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	05 Nov 2020 21:53:24
User entered ' Nov ' (non-conformant).	Erynn McKinley (b) (4)	05 Nov 2020 21:53:24
	(b) (4)	
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	05 Nov 2020 21:50:57
User entered '5 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:50:57
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:36
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 21:53:09
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 21:50:57
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'VISIT2'	(b) (4), (b) (6) System	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:56:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:42:34

US3242288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered '1'	(b) (4), (b) (6) System	27 Oct 2020 13:42:34

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:18

US3242288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'I'	(b) (4), (b) (6) System	27 Oct 2020 13:43:18

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:44:01

US3242288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'I'	(b) (4), (b) (6) System	27 Oct 2020 13:44:01

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered empty.	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:30
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'I'	(b) (4), (b) (6) System	29 Oct 2020 18:35:30

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:12
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:53:50
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:12
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 21:53:50
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:12
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	05 Nov 2020 21:53:50
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'VISIT3'	(b) (4), (b) (6) System	05 Nov 2020 21:53:50

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '15:58'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered '5 Nov 2020 15:58'	(b) (4), (b) (6) System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '97.8' F	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '56'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'bpm'	(b) (4), (b) (6) System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '16'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'breaths/min'	(b) (4), (b) (6) System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '124'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'mmHg'	(b) (4), (b) (6) System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '76'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered 'mmHg'	(b) (4), (b) (6) System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 07:20:24

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 07:20:24

US3242288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:22
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:57
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:22
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 21:54:57
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:27
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:04
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:27
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:04
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:27
User entered '16:28'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:04
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered '5 Nov 2020 16:28'	(b) (4), (b) (6) System	05 Nov 2020 21:55:04

US3242288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:07
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 21:55:07

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 64'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-05T16:05:40', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bcb522b6-d153-44eb-a4b7-afa452cea003'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Nov 2020 21:05:53

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-05T16:05:43', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bcb522b6-d153-44eb-a4b7-afa452cea003'	(b) (4), (b) (6)	
	System	05 Nov 2020 21:05:53
User entered 'No (N)'	System	05 Nov 2020 21:05:53

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-05T16:05:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bcb522b6-d153-44eb-a4b7-afa452cea003'	(b) (4), (b) (6) System	05 Nov 2020 21:05:53
User entered '05 Nov 2020 16:05:51'	System	05 Nov 2020 21:05:53

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 71'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-11T10:28:58', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd0b9fcc5-266f-4f8e-ab9c-656d3f2558eb'	(b) (4), (b) (6)	
	System	11 Nov 2020 15:29:13
User entered 'No (N)'	System	11 Nov 2020 15:29:13

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-11T10:29:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd0b9fcc5-266f-4f8e-ab9c-656d3f2558eb'	(b) (4), (b) (6)	
	System	11 Nov 2020 15:29:13
User entered 'No (N)'	System	11 Nov 2020 15:29:13

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-11T10:29:11', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd0b9fcc5-266f-4f8e-ab9c-656d3f2558eb'	(b) (4), (b) (6) System	11 Nov 2020 15:29:13
User entered '11 Nov 2020 10:29:11'	System	11 Nov 2020 15:29:13

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 78'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-17T11:35:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'eec088f6-ab2b-45aa-8709-16452ac1a103'	(b) (4), (b) (6)	
	System	17 Nov 2020 16:35:10
User entered 'No (N)'	System	17 Nov 2020 16:35:10

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-17T11:35:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'eec088f6-ab2b-45aa-8709-16452ac1a103'	(b) (4), (b) (6)	
	System	17 Nov 2020 16:35:10
User entered 'No (N)'	System	17 Nov 2020 16:35:10

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-17T11:35:06', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'eec088f6-ab2b-45aa-8709-16452ac1a103'	(b) (4), (b) (6)	
	System	17 Nov 2020 16:35:10
User entered '17 Nov 2020 11:35:06'	System	17 Nov 2020 16:35:10

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:29:23
	(b) (4), (b) (6)	
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2020-11-25T09:33:20', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '5e7b3ba1-5abf-477f-8268-8597d310c2ce'	System	25 Nov 2020 14:33:30
User entered 'No (N)'	System	25 Nov 2020 14:33:30

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2020-11-25T09:33:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '5e7b3ba1-5abf-477f-8268-8597d310c2ce'	System	25 Nov 2020 14:33:30
User entered 'No (N)'	System	25 Nov 2020 14:33:30

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-25T09:33:26', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '5e7b3ba1-5abf-477f-8268-8597d310c2ce'	System	25 Nov 2020 14:33:30
User entered '25 Nov 2020 09:33:26'	System	25 Nov 2020 14:33:30

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2020-11-28T13:50:48', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '540a9e17-4285-4dfc-9da3-73dd047b8d5c'	System	28 Nov 2020 18:50:58
User entered 'No (N)'	System	28 Nov 2020 18:50:58

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2020-11-28T13:50:50', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '540a9e17-4285-4dfc-9da3-73dd047b8d5c'	System	28 Nov 2020 18:50:58
User entered 'No (N)'	System	28 Nov 2020 18:50:58

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-28T13:50:54', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '540a9e17-4285-4dfc-9da3-73dd047b8d5c'	System	28 Nov 2020 18:50:58
User entered '28 Nov 2020 13:50:54'	System	28 Nov 2020 18:50:58

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2020-12-08T12:07:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'acc07722-342c-4fbf-920b-d17438727992'	System	08 Dec 2020 17:07:54
User entered 'No (N)'	System	08 Dec 2020 17:07:54

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2020-12-08T12:07:45', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'acc07722-342c-4fbf-920b-d17438727992'	System	08 Dec 2020 17:07:54
User entered 'No (N)'	System	08 Dec 2020 17:07:54

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-12-08T12:07:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'acc07722-342c-4fbf-920b-d17438727992' User entered '08 Dec 2020 12:07:49'	System	08 Dec 2020 17:07:54
	System	08 Dec 2020 17:07:54

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2020-12-15T08:13:48', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4e67a7b6-a3cf-4b35-8835-0cb9ed6ee17b'	System	15 Dec 2020 13:14:03
User entered 'No (N)'	System	15 Dec 2020 13:14:03

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2020-12-15T08:13:55', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4e67a7b6-a3cf-4b35-8835-0cb9ed6ee17b'	System	15 Dec 2020 13:14:03
User entered 'No (N)'	System	15 Dec 2020 13:14:03

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-12-15T08:13:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4e67a7b6-a3cf-4b35-8835-0cb9ed6ee17b'	System	15 Dec 2020 13:14:03
User entered '15 Dec 2020 08:13:59'	System	15 Dec 2020 13:14:03

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2020-12-22T17:03:28', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd48f10cf-47be-464b-9fda-06cb159641fa'	System	22 Dec 2020 22:03:48
User entered 'No (N)'	System	22 Dec 2020 22:03:48

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2020-12-22T17:03:30', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd48f10cf-47be-464b-9fda-06cb159641fa'	System	22 Dec 2020 22:03:48
User entered 'No (N)'	System	22 Dec 2020 22:03:48

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-12-22T17:03:33', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd48f10cf-47be-464b-9fda-06cb159641fa' User entered '22 Dec 2020 17:03:33'	System	22 Dec 2020 22:03:48
	System	22 Dec 2020 22:03:48

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2020-12-29T08:40:54', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '29c268f4-1ea1-4af1-956d-9fcb49da8a4c'	System	29 Dec 2020 13:41:27
User entered 'No (N)'	System	29 Dec 2020 13:41:27

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2020-12-29T08:40:58', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '29c268f4-1ea1-4af1-956d-9fcb49da8a4c'	System	29 Dec 2020 13:41:27
User entered 'No (N)'	System	29 Dec 2020 13:41:27

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-12-29T08:41:02', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '29c268f4-1ea1-4af1-956d-9fcb49da8a4c'	System	29 Dec 2020 13:41:27
User entered '29 Dec 2020 08:41:02'	System	29 Dec 2020 13:41:27

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2021-01-05T14:49:14', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '37597eb6-95f0-40c6-adca-4744f15cd756'	System	05 Jan 2021 19:49:35
User entered 'No (N)'	System	05 Jan 2021 19:49:35

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2021-01-05T14:49:25', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '37597eb6-95f0-40c6-adca-4744f15cd756'	System	05 Jan 2021 19:49:35
User entered 'No (N)'	System	05 Jan 2021 19:49:35

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2021-01-05T14:49:30', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '37597eb6-95f0-40c6-adca-4744f15cd756'	System	05 Jan 2021 19:49:35
User entered '05 Jan 2021 14:49:30'	System	05 Jan 2021 19:49:35

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2021-01-13T09:18:45', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2f640495-afb8-4beb-8eb9-9c67e6ff459c'	System	13 Jan 2021 14:18:56
User entered 'No (N)'	System	13 Jan 2021 14:18:56

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2021-01-13T09:18:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2f640495-afb8-4beb-8eb9-9c67e6ff459c'	System	13 Jan 2021 14:18:56
User entered 'No (N)'	System	13 Jan 2021 14:18:56

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2021-01-13T09:18:53', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2f640495-afb8-4beb-8eb9-9c67e6ff459c' User entered '13 Jan 2021 09:18:53'	System	13 Jan 2021 14:18:56
	System	13 Jan 2021 14:18:56

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (724e798f86573f6e)', Time: '2021-01-16T09:37:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b80532e8-caf2-4a65-8134-bd96cbfccf01'	System	16 Jan 2021 14:38:23
User entered 'No (N)'	System	16 Jan 2021 14:38:23

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (724e798f86573f6e)', Time: '2021-01-16T09:38:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b80532e8-caf2-4a65-8134-bd96cbfccf01'	System	16 Jan 2021 14:38:23
User entered 'No (N)'	System	16 Jan 2021 14:38:23

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2021-01-16T09:38:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b80532e8-caf2-4a65-8134-bd96cbfccf01'	System	16 Jan 2021 14:38:23
User entered '16 Jan 2021 09:38:08'	System	16 Jan 2021 14:38:23

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-01-27T15:10:14', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4c5b7c80-5055-4daf-888c-e54acb22b282'	System	27 Jan 2021 20:10:38
User entered 'No (N)'	System	27 Jan 2021 20:10:38

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-01-27T15:10:16', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4c5b7c80-5055-4daf-888c-e54acb22b282'	System	27 Jan 2021 20:10:38
User entered 'No (N)'	System	27 Jan 2021 20:10:38

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-01-27T15:10:22', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4c5b7c80-5055-4daf-888c-e54acb22b282'	System	27 Jan 2021 20:10:38
User entered '27 Jan 2021 15:10:22'	System	27 Jan 2021 20:10:38

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-01-30T11:17:26', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '47a7e529-c9ed-4d11-a059-2b07a307ddc5'	System	30 Jan 2021 16:17:49
User entered 'No (N)'	System	30 Jan 2021 16:17:49

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-01-30T11:17:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '47a7e529-c9ed-4d11-a059-2b07a307ddc5'	System	30 Jan 2021 16:17:49
User entered 'No (N)'	System	30 Jan 2021 16:17:49

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-01-30T11:17:32', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '47a7e529-c9ed-4d11-a059-2b07a307ddc5' User entered '30 Jan 2021 11:17:32'	System	30 Jan 2021 16:17:49
	System	30 Jan 2021 16:17:49

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-02-06T00:17:01', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'afe4e1b3-fc97-4daa-86dd-0da2d96df1ed'	System	06 Feb 2021 05:17:10
User entered 'No (N)'	System	06 Feb 2021 05:17:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-02-06T00:17:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'afe4e1b3-fc97-4daa-86dd-0da2d96df1ed'	System	06 Feb 2021 05:17:10
User entered 'No (N)'	System	06 Feb 2021 05:17:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-06T00:17:07', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'afe4e1b3-fc97-4daa-86dd-0da2d96df1ed'	System	06 Feb 2021 05:17:10
User entered '06 Feb 2021 00:17:07'	System	06 Feb 2021 05:17:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-02-17T10:41:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed410a9b-428b-4aec-ac17-43b8adaf632d'	System	17 Feb 2021 15:41:12
User entered 'No (N)'	System	17 Feb 2021 15:41:12

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-02-17T10:41:07', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed410a9b-428b-4aec-ac17-43b8adaf632d'	System	17 Feb 2021 15:41:12
User entered 'No (N)'	System	17 Feb 2021 15:41:12

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-17T10:41:09', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed410a9b-428b-4aec-ac17-43b8adaf632d'	System	17 Feb 2021 15:41:12
User entered '17 Feb 2021 10:41:09'	System	17 Feb 2021 15:41:12

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-02-20T10:06:36', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '8504eaef-ddef-4c00-9e56-4050a57c06c9'	System	20 Feb 2021 15:06:47
User entered 'No (N)'	System	20 Feb 2021 15:06:47

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-02-20T10:06:38', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '8504eaef-ddef-4c00-9e56-4050a57c06c9'	System	20 Feb 2021 15:06:47
User entered 'No (N)'	System	20 Feb 2021 15:06:47

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-20T10:06:40', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '8504eaef-ddef-4c00-9e56-4050a57c06c9'	System	20 Feb 2021 15:06:47
User entered '20 Feb 2021 10:06:40'	System	20 Feb 2021 15:06:47

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-02-27T10:21:24-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ff9515c3-55f0-4c21-8bc8-eeeeaf9e1ffd' User entered 'No (N)'	System	27 Feb 2021 15:21:38
	System	27 Feb 2021 15:21:38

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-02-27T10:21:26-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ff9515c3-55f0-4c21-8bc8-eeeeaf9e1ffd'	System	27 Feb 2021 15:21:38
User entered 'No (N)'	System	27 Feb 2021 15:21:38

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-27T10:21:30-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ff9515c3-55f0-4c21-8bc8-eeeeaf9e1ffd'	System	27 Feb 2021 15:21:38
User entered '27 Feb 2021 10:21:30'	System	27 Feb 2021 15:21:38

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-03-06T00:09:11-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '62078515-0eed-4222-961d-de1a8fd26aa1'	System	06 Mar 2021 05:09:36
User entered 'No (N)'	System	06 Mar 2021 05:09:36

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-03-06T00:09:14-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '62078515-0eed-4222-961d-de1a8fd26aa1'	System	06 Mar 2021 05:09:36
User entered 'No (N)'	System	06 Mar 2021 05:09:36

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-03-06T00:09:17-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '62078515-0eed-4222-961d-de1a8fd26aa1' User entered '06 Mar 2021 00:09:17'	System	06 Mar 2021 05:09:36
	System	06 Mar 2021 05:09:36

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-03-13T00:01:31-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'e06bc758-51a1-4704-99c5-6cf85fde408b' User entered 'No (N)'	System	13 Mar 2021 05:02:46
	System	13 Mar 2021 05:02:46

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-03-13T00:01:34-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'e06bc758-51a1-4704-99c5-6cf85fde408b'	System	13 Mar 2021 05:02:46
User entered 'No (N)'	System	13 Mar 2021 05:02:46

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-03-13T00:01:38-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'e06bc758-51a1-4704-99c5-6cf85fde408b' User entered '13 Mar 2021 00:01:38'	System	13 Mar 2021 05:02:46
	System	13 Mar 2021 05:02:46

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-03-24T11:10:05-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4d0e384c-40c1-4cfa-842e-bd2b030b05d2'	System	24 Mar 2021 15:10:21
User entered 'No (N)'	System	24 Mar 2021 15:10:21

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-03-24T11:09:37-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4d0e384c-40c1-4cfa-842e-bd2b030b05d2'	System	24 Mar 2021 15:10:21
User entered 'No (N)'	System	24 Mar 2021 15:10:21

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-03-24T11:10:12-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4d0e384c-40c1-4cfa-842e-bd2b030b05d2'	System	24 Mar 2021 15:10:21
User entered '24 Mar 2021 11:10:12'	System	24 Mar 2021 15:10:21

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 (69acd84727cda56c)', Time: '2021-03-30T18:13:31-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '5b79b942-162d-40a2-8f31-2ddc7b567502'	System	30 Mar 2021 22:14:09
User entered 'No (N)'	System	30 Mar 2021 22:14:09

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-03-30T18:13:33-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '5b79b942-162d-40a2-8f31-2ddc7b567502'	System	30 Mar 2021 22:14:09
User entered 'No (N)'	System	30 Mar 2021 22:14:09

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-03-30T18:13:36-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '5b79b942-162d-40a2-8f31-2ddc7b567502'	System	30 Mar 2021 22:14:09
User entered '30 Mar 2021 18:13:36'	System	30 Mar 2021 22:14:09

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-04-06T09:08:45-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97c24476-0270-4322-aa33-c8ebab45a41c' User entered 'No (N)'	System	06 Apr 2021 13:08:52
	System	06 Apr 2021 13:08:52

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-04-06T09:08:47-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97c24476-0270-4322-aa33-c8ebab45a41c' User entered 'No (N)'	System	06 Apr 2021 13:08:52
	System	06 Apr 2021 13:08:52

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-04-06T09:08:49-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97c24476-0270-4322-aa33-c8ebab45a41c' User entered '06 Apr 2021 09:08:49'	System	06 Apr 2021 13:08:52
	System	06 Apr 2021 13:08:52

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-04-10T09:54:52-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '95b573eb-3b4d-4771-9636-5ab99fbc5f88'	System	10 Apr 2021 13:55:04
User entered 'No (N)'	System	10 Apr 2021 13:55:04

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-04-10T09:54:54-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '95b573eb-3b4d-4771-9636-5ab99fbc5f88'	System	10 Apr 2021 13:55:04
User entered 'No (N)'	System	10 Apr 2021 13:55:04

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-04-10T09:54:59-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '95b573eb-3b4d-4771-9636-5ab99fbc5f88'	System	10 Apr 2021 13:55:04
User entered '10 Apr 2021 09:54:59'	System	10 Apr 2021 13:55:04

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

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 (69acd84727cda56c)', Time: '2021-04-17T09:36:57-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2d25b321-23d9-4a1f-bec3-bf728fe0bed8'	System	17 Apr 2021 13:37:09
User entered 'No (N)'	System	17 Apr 2021 13:37:09

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-04-17T09:37:00-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2d25b321-23d9-4a1f-bec3-bf728fe0bed8'	System	17 Apr 2021 13:37:09
User entered 'No (N)'	System	17 Apr 2021 13:37:09

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-04-17T09:37:02-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2d25b321-23d9-4a1f-bec3-bf728fe0bed8'	System	17 Apr 2021 13:37:09
User entered '17 Apr 2021 09:37:02'	System	17 Apr 2021 13:37:09

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-04-27T10:03:46-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '987344a3-b3e5-4f0f-82ce-b8459d0bc68f' User entered 'No (N)'	System	29 Apr 2021 01:40:12

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-04-27T10:03:48-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '987344a3-b3e5-4f0f-82ce-b8459d0bc68f' User entered 'No (N)'	System	29 Apr 2021 01:40:12

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-04-27T10:03:50-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '987344a3-b3e5-4f0f-82ce-b8459d0bc68f' User entered '27 Apr 2021 10:03:50'	System	29 Apr 2021 01:40:12

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[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 (69acd84727cda56c)', Time: '2021-05-03T12:02:23-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'e5a19067-dddf-41eb-8e25-2e9d049034ae'	System	03 May 2021 16:09:52
User entered 'No (N)'	System	03 May 2021 16:09:52

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

Have you been exposed to someone with 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 (69acd84727cda56c)', Time: '2021-05-03T12:02:31-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'e5a19067-dddf-41eb-8e25-2e9d049034ae'	System	03 May 2021 16:09:52
User entered 'No (N)'	System	03 May 2021 16:09:52

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-05-03T12:02:33-04:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'e5a19067-dddf-41eb-8e25-2e9d049034ae' User entered '03 May 2021 12:02:33'	System	03 May 2021 16:09:52
	System	03 May 2021 16:09:52

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:10:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:17:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-27T10:21:38-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '07c89f47-44ea-4a10-9eb7-676cf281d5ec'	System	27 Feb 2021 15:22:01
User entered 'Yes (Y)'	System	27 Feb 2021 15:22:01

US3242288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:10:30

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:17:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-27T10:21:46-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '07c89f47-44ea-4a10-9eb7-676cf281d5ec'	System	27 Feb 2021 15:22:01
User entered 'No (N)'	System	27 Feb 2021 15:22:01

US3242288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:10:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:17:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (69acd84727cda56c)', Time: '2021-02-27T10:21:50-05:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '07c89f47-44ea-4a10-9eb7-676cf281d5ec'	System	27 Feb 2021 15:22:01
User entered '27 Feb 2021 10:21:50'	System	27 Feb 2021 15:22:01

US3242288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	18 Dec 2020 00:05:33
	(b) (4)	

US3242288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered '1 Dec 2020'	Erynn McKinley (b) (4)	18 Dec 2020 00:05:33
	(b) (4)	

US3242288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	18 Dec 2020 00:05:33
	(b) (4)	

US3242288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered empty.	Erynn McKinley (b) (4)	18 Dec 2020 00:05:33
	(b) (4)	

US3242288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	18 Dec 2020 00:05:40
	(b) (4)	

US3242288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:24
User entered '1'	(b) (4), (b) (6) System	18 Dec 2020 00:05:40

US3242288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:36
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 19:15:52
	(b) (4)	

US3242288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:36
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '10 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 19:15:52
	(b) (4)	

US3242288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:36
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	12 Jan 2021 19:15:52
	(b) (4)	

US3242288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:36
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 19:15:52
	(b) (4)	

US3242288

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 19:15:55
	(b) (4)	

US3242288

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 19:15:55

US3242288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:41
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	03 Feb 2021 21:56:34
	(b) (4)	

US3242288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:41
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '3 Feb 2021'	Erynn McKinley (b) (4)	03 Feb 2021 21:56:34
	(b) (4)	

US3242288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:41
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	03 Feb 2021 21:56:34
	(b) (4)	

US3242288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:41
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	03 Feb 2021 21:56:34
	(b) (4)	

US3242288

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:04:55
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	03 Feb 2021 21:56:37
	(b) (4)	

US3242288

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered 'I'	(b) (4), (b) (6) System	03 Feb 2021 21:56:37

US3242288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:05:01
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	04 Mar 2021 21:54:05
	(b) (4)	

US3242288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:05:01
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered '04 Mar 2021'	Erynn McKinley (b) (4)	04 Mar 2021 21:54:05
	(b) (4)	

US3242288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:05:01
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	04 Mar 2021 21:54:05
	(b) (4)	

US3242288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:05:01
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	04 Mar 2021 21:54:05
	(b) (4)	

US3242288

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:05:07
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	04 Mar 2021 21:54:07
	(b) (4)	

US3242288

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered 'I'	(b) (4), (b) (6) System	04 Mar 2021 21:54:07

US3242288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:28
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:30
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:28
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered '30 Mar 2021'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:30
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:28
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:30
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered 'VISIT4'	(b) (4), (b) (6) System	30 Mar 2021 20:41:30

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:41:40

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:41:40

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:41:40

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:41:40

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:43
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:40
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:41:40

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:54:43

US3242288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:54:43

US3242288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:16
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:44
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:16
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 20:41:44
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:03
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:54
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:03
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered '30 Mar 2021'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:54
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:47:03
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered '16:34'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:54
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered '30 Mar 2021 16:34'	(b) (4), (b) (6) System	30 Mar 2021 20:41:54

US3242288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:46:49
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:59:01
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Mar 2021 20:41:58
	(b) (4)	

US3242288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:54:43
User entered '1'	(b) (4), (b) (6) System	30 Mar 2021 20:41:58

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:10:30

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:09:43
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:10:30

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:09:43
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 14:11:40
User entered '09:12' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Sep 2020 14:11:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 14:10:49
User entered '12:' (non-conformant).	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:10:30

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:09:43
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 14:11:40
User entered '11 Sep 2020 12:.' (non-conformant).	System	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:10:30

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:09:43
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User entered 'Safety Call (Safety Call)'	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:10:30

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:09:43
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 1 (Day 1)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '9 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:35:00
User closed query 'Per CDM: It appears that O2 Saturation for Day 1 & Day 2 and Temperature for Day 1 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:39:12
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 14:38:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 14:38:00
Query 'Per CDM: It appears that O2 Saturation for Day 1 & Day 2 and Temperature for Day 1 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	07 Jan 2021 14:37:50
User opened query 'Per CDM: It appears that O2 Saturation for Day 1 & Day 2 and Temperature for Day 1 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:51:12
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered '97'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	07 Jan 2021 14:38:00
User entered empty.	System	18 Sep 2020 16:40:17
User entered '%'	System	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:35:00
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 14:38:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 14:38:00
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered '99.6' F	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 2 (Day 2)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User closed query 'Per CDM; Please reconcile the year.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:46:23
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:49:13
Query 'Per CDM; Please reconcile the year.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	11 Nov 2020 22:37:48
DataPoint Un-verified.	Donna Toepfer (b) (4)	11 Nov 2020 22:37:41
User entered '10 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Nov 2020 22:37:41
User opened query 'Per CDM; Please reconcile the year.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 21:47:26
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '10 Sep 2010' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered '12 Sep 2010'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:35:00
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 14:38:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 14:38:12
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered '97'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	07 Jan 2021 14:38:12
User entered empty.	System	18 Sep 2020 16:42:39
User entered '%'	System	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '100.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered '99.8' F	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '11 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered '13 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.6' F	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 4 (Day 4)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '12 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered '14 Sep 2020'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered '96'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.8' F	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '13 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered '16 Sep 2020'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered '98'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered '99.9' F	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 6 (Day 6)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '14 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:48:27
User entered '16 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:48:27
User entered '99.1' F	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:48:27
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '15 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered '17 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered '97'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.9' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered '99.2' F	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 8 (Day 8)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '16 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.1' F	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '17 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.2' F	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 10 (Day 10)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '18 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.1' F	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 11 (Day 11)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '19 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.9' F	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 12 (Day 12)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '20 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.1' F	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 13 (Day 13)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '21 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.9' F	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User entered 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '22 Sep 2020'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.8' F	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User closed query 'Per CDM RQ: Previous response noted. Please update O2 Saturation Units as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:47:20
Query 'Per CDM RQ: Previous response noted. Please update O2 Saturation Units as appropriate.' answered with 'O2 saturation was not updated, other symptoms were missing. O2 value is correct as entered' (Site from DM).	Donna Toepfer (b) (4)	21 Apr 2021 14:54:13
User opened query 'Per CDM RQ: Previous response noted. Please update O2 Saturation Units as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:48:25
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 11 Sep 2020 symptom log on log line 15. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:48:25
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 11 Sep 2020 symptom log on log line 15. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	20 Apr 2021 13:42:28
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 11 Sep 2020 symptom log on log line 15. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:27:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
User entered 'Day 15 (Day 15)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
User closed query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:25:29
Query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08OCT2020. Please reconcile or clarify.' answered with 'symptoms ended' (Site from DM).	Donna Toepfer (b) (4)	09 Nov 2020 14:14:50
User opened query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:08:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User entered '%'	System	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.7' F	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:29:30
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:39
DataPoint Un-verified.	(b) (4)	
	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:29:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:39
DataPoint Un-verified.	(b) (4)	
	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:29:35
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:39
DataPoint Un-verified.	(b) (4)	
	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:29:37
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:39
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 13:40:02
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:18:02
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirm, positive' (Site from System).	Donna Toepfer (b) (4)	14 Sep 2020 19:18:14
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	14 Sep 2020 19:18:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[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)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:30

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:13
User entered 'I'	System	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
User closed query 'Per CDM: it appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are recorded as NO yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 14:18:24
Query 'Per CDM: it appears that both 'Did the subject Donna Toepfer (b) (4) have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are recorded as NO yet data is present. Please review and reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Jan 2021 15:37:45
User opened query 'Per CDM: it appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are recorded as NO yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	03 Jan 2021 06:27:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Form: Covid-19 Severity Assessment

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 14:06:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 14:06:24
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 14:06:24
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 14:03:34
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:35:16
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Jan 2021 15:37:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Jan 2021 15:37:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

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Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:35:16
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Jan 2021 15:37:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Jan 2021 15:37:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

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Generated On: 11 Aug 2021 22:10:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:35:16
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Jan 2021 15:37:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Jan 2021 15:37:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Generated On: 11 Aug 2021 22:10:30

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:10:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:10:30

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:11:53
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:58
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:33:17

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Re-query: Please confirm the Date of Collection for the Day 3 Saliva sample, since GCL has Day 3 recorded as 15SEP2020, and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:44:17
Query 'Per GCL Lab Reconciliation: Re-query: Please confirm the Date of Collection for the Day 3 Saliva sample, since GCL has Day 3 recorded as 15SEP2020, and update if appropriate.' answered with 'confirm date should be 13 Sep 2020' (Site from DM).	Donna Toepfer (b) (4)	03 Nov 2020 17:26:18
User opened query 'Per GCL Lab Reconciliation: Re-query: Please confirm the Date of Collection for the Day 3 Saliva sample, since GCL has Day 3 recorded as 15SEP2020, and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:37:11
User closed query 'Per GCL Lab Reconciliation: Saliva Sample day 3 reported under Illness visit is dated 15Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:37:11
Query 'Per GCL Lab Reconciliation: Saliva Sample day 3 reported under Illness visit is dated 15Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'symptom log does not match saliva log' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 19:34:03
User opened query 'Per GCL Lab Reconciliation: Saliva Sample day 3 reported under Illness visit is dated 15Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:16:30
User accepted default value 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:41:53
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '1F60FH3' (Site from DM).	Donna Toepfer (b) (4)	20 Jan 2021 19:46:13
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:40:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:40:10
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with '917903314693' (Site from DM).	Donna Toepfer (b) (4)	08 Jan 2021 22:05:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:33:10

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:42:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'confirmed receipt from lab' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 13:19:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:40:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '13 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:10:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '15 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:30

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User closed query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 7 in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:42:06
Query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 7 in query response, thank you.' answered with 'Day 7 is 17 Sep 2020' (Site from DM).	Donna Toepfer (b) (4)	22 Jan 2021 16:28:18
User opened query 'Per GCL Lab Recon: Re-query: Saliva: Please confirm the correct date for Day 7 in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:03:36
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 17SEP2020 is reported in PPD central lab with 21SEP2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:03:36
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 17SEP2020 is reported in PPD central lab with 21SEP2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'dcf submitted' (Site from DM).	Donna Toepfer (b) (4)	08 Jan 2021 21:00:13
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 17SEP2020 is reported in PPD central lab with 21SEP2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:28:33
Query 'US3242288 ' canceled (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:27:51
User opened query 'US3242288 ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:27:26
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17SEP2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:42:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17SEP2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'confirmed receipt from lab' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 13:19:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17SEP2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:41:01
User closed query 'Per GCL Lab Reconciliation: Saliva Sample reported under Illness visit is dated 21Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:19:58
Query 'Per GCL Lab Reconciliation: Saliva Sample reported under Illness visit is dated 21Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'confirm date is 17 Sep 2020' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 19:35:10

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva Sample reported under Illness visit is dated 21Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:17:31
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '17 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:44:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Date is correct 19Sep2020, no Saliva sample on 21Sep2020 per source' (Site from DM).	Donna Toepfer (b) (4)	06 Nov 2020 13:17:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:51:59
User accepted default value 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:10:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19SEP2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:42:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19SEP2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'confirmed receipt from lab' (Site from DM).	Donna Toepfer (b) (4)	08 Dec 2020 13:19:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19SEP2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:41:24
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '19 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:10:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:19:09
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered with 'will update when completed' (Site from System).	Donna Toepfer (b) (4)	21 Sep 2020 18:29:40
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:29:00
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 25SEP2020 for Day 14 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Recon: Saliva: Samples dated 25SEP2020 for Day 14 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:18:53
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:09:37
	Donna Toepfer (b) (4)	29 Oct 2020 14:09:31
User entered '25 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:09:31
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 25SEP2020 for Day 14 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 06:33:46
	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:10:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:19:15
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered with 'will update when subject completes' (Site from System).	Donna Toepfer (b) (4)	21 Sep 2020 18:29:51
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:29:00
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 02OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Recon: Saliva: Sample dated 02OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:19:24
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:09:52
	Donna Toepfer (b) (4)	29 Oct 2020 14:09:47
User entered '02 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:09:47
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 02OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:34:23
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:10:30

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:10:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:19:24
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered with 'will update when subject completes' (Site from System).	Donna Toepfer (b) (4)	21 Sep 2020 18:30:03
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:29:00
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
User entered '8 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 15:36:44
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:51
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	21 Sep 2020 18:29:23
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 17:48:08
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 17:47:48
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 17:36:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:51
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[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 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:51
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User entered 'SICKD1'	System	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '14:20'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User entered '11 Sep 2020 14:20'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '67' in	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19
DataPoint set to visible.	System	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '209' lb	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19
DataPoint set to visible.	System	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '99.6' F	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '60'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User entered 'bpm'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 19:19:28
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	14 Sep 2020 19:19:28
User entered '14' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Sep 2020 19:19:28
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 19:19:19
User entered '174'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User entered 'breaths/min'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '128'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User entered 'mmHg'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '70'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User entered 'mmHg'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02

US3242288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:25
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:41

US3242288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:25
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:22:37
User entered '11 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Sep 2020 19:22:37
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:19:41
User entered '14 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:41

US3242288

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:10:30

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:39:03

US3242288

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:02
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:34
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:39:03

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:14
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:14
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:01
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Nov 2020 12:42:56
User entered '08 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:42:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:41
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[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 21:36:14
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:41
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:14
User entered 'SICKD28'	System	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '07:59'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User entered '8 Oct 2020 07:59'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '67' in	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23
DataPoint set to visible.	System	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '209' lb	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23
DataPoint set to visible.	System	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '97.3' F	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered empty.	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '60'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User entered 'bpm'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '16'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User entered 'breaths/min'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '128'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User entered 'mmHg'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '82'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08
User entered 'mmHg'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:08

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:55
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:35

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:55
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:35

US3242288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:10:30

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:54

US3242288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:10:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:36:00
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:01
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:54

US3242288

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

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:36

US3242288

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

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '07 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:36

US3242288

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

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[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 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:53
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:36

US3242288

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

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	07 Jan 2021 23:01:36

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '07 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:08:34
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:08:00

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 12:21:54
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject did not receive 2nd dose due to covid positive' (Site from System).	Donna Toepfer (b) (4)	07 Jan 2021 23:10:30
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	07 Jan 2021 23:10:12
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	07 Jan 2021 23:08:03
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	07 Jan 2021 23:08:03
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	07 Jan 2021 23:01:53
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:08:34
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:08:00

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '07 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:05:02
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:02:16
User closed query 'Per CDM: As per CCG, Data is required, please update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:59:03
Query 'Per CDM: As per CCG, Data is required, please update accordingly. Else clarify.' answered with 'subject did not receive dose 2' (Site from DM).	Donna Toepfer (b) (4)	08 Jan 2021 22:07:06
User opened query 'Per CDM: As per CCG, Data is required, please update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:33:54
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 23:10:12
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 23:08:03
User entered empty.	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:31:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	07 Jan 2021 23:01:53

US3242288

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User entered 'I'	System	01 Feb 2021 22:02:16
User entered empty.	System	07 Jan 2021 23:10:12
User entered 'I'	System	07 Jan 2021 23:08:03
User entered empty.	System	07 Jan 2021 23:01:53

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '67' in	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '209' lb	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
DataPoint set to visible.	System	01 Feb 2021 22:02:16
DataPoint set to invisible.	System	07 Jan 2021 23:10:12
User entered '32.80247'	System	07 Jan 2021 23:08:58
DataPoint set to visible.	System	07 Jan 2021 23:08:03

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '67' in	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '209' lb	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
DataPoint set to visible.	System	01 Feb 2021 22:02:16
DataPoint set to invisible.	System	07 Jan 2021 23:10:12
User entered '32.80247'	System	07 Jan 2021 23:08:58
DataPoint set to visible.	System	07 Jan 2021 23:08:03

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '7 Jan 2021'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '16:58'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '7 Jan 2021 16:58'	(b) (4), (b) (6) System	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '97.8' F	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '68'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'bpm'	(b) (4), (b) (6) System	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '16'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '132'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'mmHg'	(b) (4), (b) (6) System	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '74'	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'mmHg'	(b) (4), (b) (6) System	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '67' in	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '209' lb	Donna Toepfer (b) (4)	07 Jan 2021 23:08:58

US3242288

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
DataPoint set to visible.	System	01 Feb 2021 22:02:16
DataPoint set to invisible.	System	07 Jan 2021 23:10:12
User entered '32.80247'	System	07 Jan 2021 23:08:58
DataPoint set to visible.	System	07 Jan 2021 23:08:03

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '7 Jan 2021'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '17:57'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '7 Jan 2021 17:57'	(b) (4), (b) (6) System	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '97.3' F	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '70'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'bpm'	(b) (4), (b) (6) System	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '16'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '128'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'mmHg'	(b) (4), (b) (6) System	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:04
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '80'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:31

US3242288

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'mmHg'	(b) (4), (b) (6) System	07 Jan 2021 23:09:31

US3242288

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:46

US3242288

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	07 Jan 2021 23:09:46

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
DataPoint set to visible.	System	01 Feb 2021 22:02:16
DataPoint set to invisible.	System	07 Jan 2021 23:10:12
User entered 'mRNA-1273'	System	07 Jan 2021 23:10:05
DataPoint set to visible.	System	07 Jan 2021 23:08:03

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '7 Jan 2021'	Donna Toepfer (b) (4)	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '17:26'	Donna Toepfer (b) (4)	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '7 Jan 2021 17:26'	(b) (4), (b) (6) System	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:16
User entered 'ONCE'	System	07 Jan 2021 23:10:05

US3242288

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	07 Jan 2021 23:10:05

US3242288

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 17:03:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:02:20

US3242288

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 17:03:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '07 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:02:20

US3242288

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 17:03:32
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '16:42'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:02:20

US3242288

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '07 Jan 2021 16:42'	(b) (4), (b) (6) System	07 Jan 2021 23:02:20

US3242288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:26
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:02:31

US3242288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:26
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '07 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:02:31

US3242288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:26
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '16:41'	Erynn McKinley (b) (4) (b) (4)	07 Jan 2021 23:02:31

US3242288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered '07 Jan 2021 16:41'	(b) (4), (b) (6) System	07 Jan 2021 23:02:31

US3242288

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

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 03:32:30
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:09:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Jan 2021 23:09:37

US3242288

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

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'I'	(b) (4), (b) (6) System	07 Jan 2021 23:09:37

US3242288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:32:41
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	14 Jan 2021 18:25:33

US3242288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:32:41
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered '14 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	14 Jan 2021 18:25:33

US3242288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:32:41
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	14 Jan 2021 18:25:33

US3242288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:32:41
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Erynn McKinley (b) (4) (b) (4)	14 Jan 2021 18:25:33

US3242288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:32:47
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	14 Jan 2021 18:25:36

US3242288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
User entered 'I'	System	14 Jan 2021 18:25:36

US3242288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:06
User entered '1'	System	14 Jan 2021 18:25:36
DataPoint set to visible.	System	14 Jan 2021 18:25:36

US3242288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:54
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:39:59
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:01:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:00:47
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	01 Feb 2021 22:00:11
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:00:11
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	01 Feb 2021 21:59:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 21:59:52
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Feb 2021 21:59:28

US3242288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:54
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered '1 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:39:59
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:01:17
User entered '14 Jan 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:00:47
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 21:59:28

US3242288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

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 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:54
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:39:59
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:01:17
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:00:47
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	01 Feb 2021 22:00:11
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	01 Feb 2021 21:59:52
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 21:59:28

US3242288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered 'OLD29'	(b) (4), (b) (6) System	01 Feb 2021 21:59:28

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:32:59
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
User entered empty.	(b) (4), (b) (6) System	01 Feb 2021 22:03:29

US3242288

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	

US3242288

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:33:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Feb 2021 22:03:37

US3242288

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:33:06
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:37

US3242288

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:33:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:59:04
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Feb 2021 22:03:44

US3242288

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:33:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered '1 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:59:04
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:44

US3242288

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 03:33:11
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User entered '16:30' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Feb 2021 22:59:04
User entered empty.	Donna Toepfer (b) (4)	01 Feb 2021 22:03:44

US3242288

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:48
	(b) (4), (b) (6)	
User entered '1 Feb 2021 16:30'	System	01 Feb 2021 22:59:04
User entered empty.	System	01 Feb 2021 22:03:44

US3242288

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:10:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:42:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Sep 2020 19:06:59
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:21

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:27
User entered 'USA-US067-2020-mRNA-1273-P301000004'	System	15 Sep 2020 15:31:19
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 15:31:19

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:00:40
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:03:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:31:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:31:36
Data point term sent to Coder	System	10 Apr 2021 13:34:31
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Apr 2021 13:34:30
Coding entries removed.	Donna Toepfer (b) (4)	10 Apr 2021 13:34:30
Signature has been broken.	Donna Toepfer (b) (4)	10 Apr 2021 13:34:30
User entered 'SAR-COV-2' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Apr 2021 13:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 00:24:09
User closed query 'Per CDM: per sponsor review, Please consider updating term to Covid-19 ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:45:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 02:39:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 02:39:53
Data point term sent to Coder	System	17 Nov 2020 02:38:42
Query 'Per CDM: per sponsor review, Please consider updating term to Covid-19 ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	17 Nov 2020 02:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 02:38:27
Coding entries removed.	Donna Toepfer (b) (4)	17 Nov 2020 02:38:27
User entered 'COVID-19' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 02:38:27
User opened query 'Per CDM: per sponsor review, Please consider updating term to Covid-19 ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 14:15:53
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:12:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 19:12:52
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 19:12:08
User entered 'SARS COVID-19'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: The event start date is reported as 09-SEP-2020 however, there were no signs or symptoms reported on this date and date of positive test was 11-SEP-2020. Please provide signs and symptoms for this date, clarify that the covid-19 swab was taken on 09-SEP-2020, or update start date to the date of positive test. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:37:15
Query 'PV Query: The event start date is reported as 09-SEP-2020 however, there were no signs or symptoms reported on this date and date of positive test was 11-SEP-2020. Please provide signs and symptoms for this date, clarify that the covid-19 swab was taken on 09-SEP-2020, or update start date to the date of positive test. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 17:02:44
User opened query 'PV Query: The event start date is reported as 09-SEP-2020 however, there were no signs or symptoms reported on this date and date of positive test was 11-SEP-2020. Please provide signs and symptoms for this date, clarify that the covid-19 swab was taken on 09-SEP-2020, or update start date to the date of positive test. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:26:28
User entered '09 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 12:23:43
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6) Donna Toepfer (b) (4)	24 Sep 2020 16:48:27 24 Sep 2020 12:23:53
User entered '23 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 12:23:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:24:26
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:18:48
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		14 Sep 2020 19:11:17
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 18:27:51
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'confirm, AE of SARS COVID 19' (Site from System).	Donna Toepfer (b) (4)	14 Sep 2020 19:12:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:11:17
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

None

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:21:37
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	05 Oct 2020 15:22:55
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 22:42:15
User entered 'I'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:48:33
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).	Donna Toepfer (b) (4)	24 Sep 2020 12:24:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Donna Toepfer (b) (4)	24 Sep 2020 12:23:43
Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 16:25:25
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).	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:37:38
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)	22 Sep 2020 15:37:36
Query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' answered with 'no known exposure' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 17:03:15
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 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 17:03:07
User opened query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19?' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:25:10
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 Sep 2020 16:24:44
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:39:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:39:20
Data point term sent to Coder	System	22 Oct 2020 17:50:11
User entered 'Worsening Hyperlipidemia'	Erynn McKinley (b) (4) (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Form: Adverse Events (2)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '29 Sep 2020'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
User entered empty.	(b) (4), (b) (6) System	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:17:18
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:17:18
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
User entered '05 Mar 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
User entered empty.	(b) (4), (b) (6) System	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'None (NONE)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '1'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:22:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:17:18
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 19:59:42
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
User entered '0'	(b) (4), (b) (6) System	22 Oct 2020 17:50:01

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:02:37
User entered '1'	(b) (4), (b) (6) System	22 Oct 2020 17:50:01

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:10:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 20:02:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:10:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:42:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:29:47
Data point term sent to Coder	System	03 Sep 2020 14:29:28
User entered 'Clonidine'	Donna Toepfer (b) (4) (b) (4) (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Hypertension'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0.1'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:30:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:30:47
Data point term sent to Coder	System	03 Sep 2020 14:29:32
User entered 'Simvastatin'	Donna Toepfer (b) (4) 	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '20'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Un UNK 2005'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Dec 2020 23:51:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Dec 2020 23:51:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Dec 2020 23:51:06
	(b) (4)	
User entered '28 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Dec 2020 23:51:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
User entered '1'	(b) (4), (b) (6) System	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
User entered '1'	(b) (4), (b) (6) System	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:09
User entered '804 (804)'	(b) (4), (b) (6) System	03 Sep 2020 14:29:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE, PRODUCTSYNONYM: ARIMIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:43:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:43:10
	(b) (4)	
Data point term sent to Coder	System	12 Jan 2021 21:42:38
Coding entries removed.	Donna Toepfer (b) (4)	12 Jan 2021 21:41:49
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE, PRODUCTSYNONYM: ARIMIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 23:54:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 23:54:23
	(b) (4)	
Data point term sent to Coder	System	17 Dec 2020 23:52:38
Coding entries removed.	Erynn McKinley (b) (4)	17 Dec 2020 23:52:22
	(b) (4)	
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE, PRODUCTSYNONYM: ARIMIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 15:57:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Donna Toepfer (b) (4) [REDACTED]	19 Oct 2020 15:57:34 19 Oct 2020 15:56:32 19 Oct 2020 15:55:53
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	30 Sep 2020 16:30:53
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE, PRODUCTSYNONYM: ARIMIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Arimidex'	Coder Import (b) (4) (b) (4) System Donna Toepfer (b) (4) [REDACTED] [REDACTED]	03 Sep 2020 14:31:41 03 Sep 2020 14:30:33 03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:38:32
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:56:05
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	12 Jan 2021 21:41:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	12 Jan 2021 21:41:49
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Jan 2021 21:41:49
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:31:42
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:52:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:52:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:22:51

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 15:56:02
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
User opened query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 05:14:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 16:30:53
	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:38:32
DataPoint Un-verified.	Donna Toepfer (b) (4)	12 Jan 2021 21:41:49
User entered 'HYPERPLASIA IN BREAST TISSUE, BILATERAL' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Jan 2021 21:41:49
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Dec 2020 23:52:22
User entered 'PROPHYLAXIS FOR HYPERPLASIA IN BREAST TISSUE, BILATERAL' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Dec 2020 23:52:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
User entered 'HYPERPLASIA IN BREAST TISSUE, Bilateral' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Prevent hyperplasia in breast tissue'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '1'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Un Aug 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:29:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 15:24:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 15:24:22
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 15:23:12
Coding entries removed.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:34:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:34:02
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 16:33:24
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:13
User entered 'FEVER(COVID-19 symptoms)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Oct 2020 15:22:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Fever'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '500'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:04:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '23 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:04:52
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:23:29
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 15:56:30
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 15:56:23
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 15:56:23
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:50:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:26
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:02:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:20:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:20:29
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Apr 2021 21:18:14
Data point term sent to Coder	System	08 Apr 2021 17:16:41
User closed query 'CDM-Coding: Please enter the active ingredient(s) of drug name DAYQUIL in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	System	08 Apr 2021 17:16:08
Query 'CDM-Coding: Please enter the active ingredient(s) of drug name DAYQUIL in drug name field and please make your changes to the reported term. Thank you. ' answered with 'updated' (Site from System).	Donna Toepfer (b) (4)	08 Apr 2021 17:16:08
Data point term sent to Coder	System	08 Apr 2021 17:15:40
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Apr 2021 17:15:04
Coding entries removed.	Donna Toepfer (b) (4)	08 Apr 2021 17:15:04
Signature has been broken.	Donna Toepfer (b) (4)	08 Apr 2021 17:15:04
User entered 'DAYQUIL(Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Apr 2021 17:15:04

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

Name of Medication

Audit	User	Time (GMT)
User opened query 'CDM-Coding: Please enter the active ingredient(s) of drug name DAYQUIL in drug name field and please make your changes to the reported term. Thank you. ' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:28:05
	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:24:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:24:23
Data point term sent to Coder Coding entries removed.	System Donna Toepfer (b) (4)	05 Oct 2020 15:23:12 05 Oct 2020 15:22:35
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:02
Data point term sent to Coder User entered 'Dayquil'	System Donna Toepfer (b) (4)	18 Sep 2020 16:33:26 18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:35
User entered 'FEVER and congestion (COVID-19 symptoms)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Oct 2020 15:22:35
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Fever'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Dec 2020 23:56:45
	(b) (4)	
User entered '2' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Dec 2020 23:56:45
	(b) (4)	
User closed query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	11 Nov 2020 02:24:56
' (Site from DM).	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
Query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify.	Donna Toepfer (b) (4)	09 Nov 2020 14:11:27
' answered with 'med is a tablet' (Site from DM).		
User opened query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	06 Nov 2020 14:08:34
' (Site from DM).		
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	28 Oct 2020 20:22:35
' (Site from DM).		
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Donna Toepfer (b) (4)	19 Oct 2020 18:24:08
' answered with 'updated' (Site from DM).		

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59
User entered '325/10/5' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:15:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '2'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Dec 2020 23:56:45
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Erynn McKinley (b) (4)	17 Dec 2020 23:56:45
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59
User entered 'mg (mg)' reason for change: Data	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59
Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'capsule (CAPSULE)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Dec 2020 23:56:45
	(b) (4)	
User entered 'capsules' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Dec 2020 23:56:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:05:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '24 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:05:12
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:23:53
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 18:24:32
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 18:24:27
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 18:24:27
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:33:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:30
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:49:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:49:24
Data point term sent to Coder	System	05 Nov 2020 22:48:40
User entered 'Influenza Vaccine'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Prophylaxis for Influenza'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0.5'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mL (mL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '12 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '12 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:34:34
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:50:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:50:31
Data point term sent to Coder	System	05 Nov 2020 22:49:42
User entered 'Crestor'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Hyperlipidemia'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '20'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '29 Sep 2020'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 05:42:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 05:42:54
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 22:51:43
User entered 'Shringrix'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Prophylaxis for shingles'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0.50'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mL (mL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:01
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED YEAST RICE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 05:48:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 05:48:29
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 22:51:43
User entered 'Red Yeast Rice'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:38:32
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:00:12
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	13 Jan 2021 12:56:34
DataPoint Un-verified.	Donna Toepfer (b) (4)	13 Jan 2021 12:56:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Jan 2021 12:56:26
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:55:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Supplement for Hyperlipidemia'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '600'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mg (mg)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'twice daily (BID)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 22:52:08
	(b) (4)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Nov 2020 22:52:08
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Nov 2020 22:51:32
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
User entered '2'	(b) (4), (b) (6) System	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:35:04
User entered '804 (804)'	(b) (4), (b) (6) System	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:00:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:00:59
Data point term sent to Coder	System	17 Dec 2020 23:59:44
User entered 'Aspirin'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Heart Health'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered '81'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered '09 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered '0'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:21:59
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 23:59:29

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:04:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:04:03
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:58:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:58:46
Data point term sent to Coder User entered 'Botox'	System Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:37 02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:46:20
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	15 Mar 2021 16:08:34
DataPoint Un-verified.	Donna Toepfer (b) (4)	12 Mar 2021 22:32:31
Signature has been broken.	Donna Toepfer (b) (4)	12 Mar 2021 22:32:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Mar 2021 22:32:31
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
User closed query 'Per CDM: Response noted 'not a mex hx to match, it is a matching elective injection'. Please review response for 'Prophylaxis' and consider if CM was used as a 'preventative' measure. Update accordingly else clarify. Thank you.' (Site from DM). Query 'Per CDM: Response noted 'not a mex hx to match, it is a matching elective injection'. Please review response for 'Prophylaxis' and consider if CM was used as a 'preventative' measure. Update accordingly else clarify. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 15:26:10
User opened query 'Per CDM: Response noted 'not a mex hx to match, it is a matching elective injection'. Please review response for 'Prophylaxis' and consider if CM was used as a 'preventative' measure. Update accordingly else clarify. Thank you.' (Site from DM). User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	Donna Toepfer (b) (4)	12 Mar 2021 22:32:36
User opened query 'Per CDM: Response noted 'not a mex hx to match, it is a matching elective injection'. Please review response for 'Prophylaxis' and consider if CM was used as a 'preventative' measure. Update accordingly else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:22:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:22:51
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' answered with 'not a mex hx to match, it is a matching elective injection' (Site from DM).	Donna Toepfer (b) (4)	11 Mar 2021 18:37:36
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:26:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'Cosmetic'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered '64'	Erynn McKinley (b) (4)	02 Mar 2021 21:58:17
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'IU (IU)'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:45:29
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4)	02 Mar 2021 21:58:17
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'UN UNK 2014'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered '0'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'UN UNK 2014'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 03:33:58
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:45:29
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
User entered empty.	System	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
User entered empty.	System	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:10:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:19:17
User entered empty.	System	02 Mar 2021 21:58:17

US3242288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:10:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:11

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:10:30

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:43
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:06
User entered '14 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:06:46

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:10:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:43
User closed query 'Per CDM: Please kindly review and update the corresponding AE log line Related to SARS- COV-2.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:39:52
Query 'Per CDM: Please kindly review and update the corresponding AE log line Related to SARS- COV-2.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	10 Apr 2021 13:34:43
User opened query 'Per CDM: Please kindly review and update the corresponding AE log line Related to SARS- COV-2.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 10:27:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:06
User entered 'Due to SARS-COV-2 (COVID)'	Donna Toepfer (b) (4)	14 Sep 2020 19:06:46

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:10:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:43
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:27:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:06
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:06:46

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:10:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '15/Sep/2020 11:31'	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:10:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:10:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '15/Sep/2020 13:24'	System	15 Sep 2020 17:24:04

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:10:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:37:48
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 17:24:04

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered	System	15 Sep 2020 15:31:19
'USA-US067-2020-MRNA-1273-P301000004'		

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:10:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '22/Sep/2020 11:37'	System	22 Sep 2020 15:38:02

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:10:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 15:38:02

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered	System	15 Sep 2020 15:31:19
'USA-US067-2020-MRNA-1273-P301000004'		

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:28:41
	(b) (4)	
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:10:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '24/Sep/2020 12:49'	System	24 Sep 2020 16:49:03

US3242288

Folder: SAE USA-US067-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:10:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:28:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 16:49:03