

US3042288 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

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US3042288

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Participant ID

US3042288

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

US3042288

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:36 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:36
Height (<i>xxx.x</i>)	165.1 cm
Weight (<i>xxx.x</i>)	106.2 kg
BMI (<i>xxx.x</i>)	38.96102 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2003

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:40:53

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

PATIENT GOES OUT IN
COMMUNITY WITHOUT A
MASK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:40:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 21:40:54

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What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 187611

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) 28 Apr 2021 21:40:54

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

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)	21 AUG 2020
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:36
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	15:41 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 15:41
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:54

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

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) 21 AUG 2020

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

Treatment Date and Time (derived) 21 AUG 2020 15:10

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	21 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:50 (24 HR)
Collection date and time (derived)	21 AUG 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	21 AUG 2020 14:42
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 21 AUG 2020 15:44

PC Open Date & Time 21 AUG 2020 15:30

PC Close Date & Time 21 AUG 2020 18:00

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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 96.7 °F

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

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

PC Time Stamp	21 AUG 2020 20:45
PC Open Date & Time	21 AUG 2020 18:55
PC Close Date & Time	22 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

98.4 °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

22 AUG 2020 18:30

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

24 AUG 2020 18:02

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

98.5 °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

25 AUG 2020 17:27

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 18:05

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:06

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

21 AUG 2020 15:45

PC Open Date & Time

21 AUG 2020 15:30

PC Close Date & Time

21 AUG 2020 18:00

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

21 AUG 2020 20:46

PC Open Date & Time

21 AUG 2020 18:55

PC Close Date & Time

22 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

22 AUG 2020 18:31

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

23 AUG 2020 18:04

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

24 AUG 2020 18:03

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

25 AUG 2020 17:28

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

26 AUG 2020 18:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

27 AUG 2020 18:06

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 15:46
PC Open Date & Time	21 AUG 2020 15:30
PC Close Date & Time	21 AUG 2020 18:00

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 20:47
PC Open Date & Time	21 AUG 2020 18:55
PC Close Date & Time	22 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

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 ☒

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EAB) (1725)

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US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:33
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:05
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:04
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:29
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

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 ☒

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EAB) (1725)

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US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:07
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:07
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3042288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT2

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:33 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:33
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3042288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

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) 21 SEP 2020

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

Treatment Date and Time (derived) 21 SEP 2020 10:00

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

What was the frequency of the study treatment dosing? ONCE

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

US3042288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

09:41 (24 HR)

Collection date and time (derived)

21 SEP 2020 09:41

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:48	21 SEP 2020 09:48
Nasopharyngeal Swab 2	No		

US3042288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:54

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

21 SEP 2020 10:36

PC Open Date & Time

21 SEP 2020 10:20

PC Close Date & Time

21 SEP 2020 12:50

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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 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	21 SEP 2020 19:17
PC Open Date & Time	21 SEP 2020 13:45
PC Close Date & Time	22 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 18:07

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 18:05

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

98.4 °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

24 SEP 2020 18:04

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:16

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

98.3 °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

26 SEP 2020 18:44

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

27 SEP 2020 19:57

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

21 SEP 2020 10:37

PC Open Date & Time

21 SEP 2020 10:20

PC Close Date & Time

21 SEP 2020 12:50

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

21 SEP 2020 19:18

PC Open Date & Time

21 SEP 2020 13:45

PC Close Date & Time

22 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

22 SEP 2020 18:07

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

23 SEP 2020 18:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

24 SEP 2020 18:05

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

25 SEP 2020 18:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

26 SEP 2020 18:45

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

27 SEP 2020 19:58

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:38
PC Open Date & Time	21 SEP 2020 10:20
PC Close Date & Time	21 SEP 2020 12:50

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 19:19
PC Open Date & Time	21 SEP 2020 13:45
PC Close Date & Time	22 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 18:08
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:07
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:06
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:18
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 18:46
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

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 ☒

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:58
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3042288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT3

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 09:00
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3042288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	09:05 (24 HR)
Collection date and time (derived)	21 OCT 2020 09:05

US3042288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 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"/>

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 18:37:30

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 18:42:19

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 06:35:00

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 18:26:24
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 DEC 2020 09:35:56
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 21:05:07

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 07:27:28
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 08:15:27

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

04 JAN 2021 07:01:27

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 10:37:59

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 18:31:04

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 14:34:10

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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	01 FEB 2021 10:37:34
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

07 FEB 2021 15:13:48

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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	14 FEB 2021 13:36:45
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 11:11:42

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

28 FEB 2021 11:31:37

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 20:07:35

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

14 MAR 2021 07:15:00

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

21 MAR 2021 09:16:14

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

28 MAR 2021 21:42:23

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

04 APR 2021 08:04:43

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 13:01:29

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 09:47:15

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 01:31:15

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 08:46:06

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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°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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 <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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 <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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 <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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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="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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 <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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 684

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

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

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

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

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

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

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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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 <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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 OCT 2022 00:01
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3042288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:57:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 08:58:24

US3042288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments PATIENT IN CONVALESCENT
PHASE AND IS BEING
CONTACTED DAILY
If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

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) _____

US3042288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

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.

US3042288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

10:56 (24 HR)

Collection date and time (derived)

19 MAR 2021 10:56

US3042288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:55

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Date of Contact	30 NOV 2020
Time of Contact	10:28
Date and Time of Contact (derived)	30 NOV 2020 10:28
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	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	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	37.0 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 DEC 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Form: Symptom Log (5)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

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

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Form: Symptom Log (6)

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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 (6)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Form: Symptom Log (8)

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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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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 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 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 DEC 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 (10)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Date	10 DEC 2020
------	-------------

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

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

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

Temperature	96.2 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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EAB) (1725)

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Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 21:40:47

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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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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Symptom Day

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Date	13 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 21:40:47

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

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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 21:40:47

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Symptom Day

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

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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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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Form: Symptom Log (16)

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Generated On: 09 Jun 2021 14:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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 (16)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (16)

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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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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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 (17)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (17)

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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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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" 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 (18)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Date	17 DEC 2020
------	-------------

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

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

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

Temperature	97.5 F
-------------	--------

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

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

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

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

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

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Form: Symptom Log (18)

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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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Form: Symptom Log (19)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" 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 (19)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

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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 30 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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 checked="" 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 (20)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

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Form: Symptom Log (20)

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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 30 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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 checked="" 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 (21)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (21)

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Generated On: 09 Jun 2021 14:57:53

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

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Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 21:40:47

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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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Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 21:40:47

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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 checked="" 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 (22)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 21:40:47

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input 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 checked="" 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 30 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	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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Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Date	27 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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"/>

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Date	28 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Date of Visit	30 NOV 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	30 NOV 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

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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 30 NOV 2020
End Date 09 DEC 2020
Oxygen Saturation 93 %

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 _____

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment

01 DEC 2020

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☒
No ☐

Start Date

01 DEC 2020

End Date

05 DEC 2020

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 21:40:48

Generated On: 09 Jun 2021 14:57:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	Yes	13 DEC 2020
Day 21	No	
Day 28	Yes	28 DEC 2020

US3042288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:28 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 10:28
Height (<i>xxx.x</i>)	165.1 cm
Weight (<i>xxx.x</i>)	106.1 kg
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:48

Generated On: 09 Jun 2021 14:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 NOV 2020

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

US3042288

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 28 Apr 2021 21:40:48

Generated On: 09 Jun 2021 14:57:53

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 NOV 2020

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 10:01
Height (xxx.x)	165.1 cm
Weight (xxx.x)	105.8 kg
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3042288

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3042288

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3042288

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 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>)	16 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3042288

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

Height	
Weight	
BMI (xxx.x)	

US3042288

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 10:06
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3042288

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 10:53
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042288

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 JAN 2021

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

US3042288

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

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) 16 JAN 2021

What was the treatment time? (00:00-23:59) 10:22 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 10:22

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

US3042288

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00-23:59)	09:49 (24 HR)
Collection date and time (derived)	16 JAN 2021 09:49

US3042288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	09:51
Collection Date and Time (derived)	16 JAN 2021 09:51

US3042288

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

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)	5 MAR 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 11:05
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

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)	5 MAR 2021
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 11:53
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3042288

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

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

US3042288

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

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) 5 MAR 2021

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 5 MAR 2021 11:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3042288

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042288

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:40:53

Generated On: 09 Jun 2021 14:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042288

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:36 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 10:36
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042288

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

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.

US3042288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:40:49

Generated On: 09 Jun 2021 14:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 APR 2021
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	02 APR 2021 10:46

US3042288

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

AEID	USA-US052-2020-MRNA-1273-P30 1000025
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	27 NOV 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)	22 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	05 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS REFERRED TO MERCY ER AS O2 STAT WAS LOW. SUBJECT WAS THEN ADMITTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

AEID	
Adverse event	DIABETES TYPE 2
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

AEID	
Adverse event	HYPERCHOLESTEROLEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

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

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

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

Yes ☒

No ☐

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

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 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 (2)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED COVID-19

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 (2)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 40

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 (3)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	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)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	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)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 (5)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 40

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) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 (7)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication ZINC SULFATE

Prophylaxis Yes ☒
No ☐

Indication COVID-19

Dose per administration 220

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 (9)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:40:46

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Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:40:46

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Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q24HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEREMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

487 of 3108

EAB) (1725)

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:40:46

Generated On: 09 Jun 2021 14:57:53

	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)	27 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3042288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:40:47

Generated On: 09 Jun 2021 14:57:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3042288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:53

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3042288

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:53

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 ☐

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/DEC/2020 19:48
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

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/DEC/2020 08:33
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

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/DEC/2020 09:58
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

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/DEC/2020 12:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/DEC/2020 22:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/JAN/2021 12:24
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

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/JAN/2021 13:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:55
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

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 21:40:52

Generated On: 09 Jun 2021 14:57:53

SAEID	USA-US052-2020-MRNA-1273-P301000025
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	
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

US3042288 (Prod: Meridian Clinical Research)

US3042288

Form: Participant Creation

Generated On: 09 Jun 2021 14:57:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered 'US3042288'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 19:54:29

US3042288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:09:17

US3042288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 19:54:31

US3042288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:09:17

US3042288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'SCRN'	(b) (4), (b) (6) System	22 Aug 2020 14:09:17

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 19:54:32

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '70'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:22

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'YEARS'	(b) (4), (b) (6) System	22 Aug 2020 14:23:22

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered '70'	(b) (4), (b) (6) System	21 Aug 2020 20:13:29

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Female (F)'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:22

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'I'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:22

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:22

US3042288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:22
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Aug 2020'	Rylea Gulick (b) (4)	21 Aug 2020 20:13:29
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'Aug 2020'	(b) (4), (b) (6) System	21 Aug 2020 20:13:29

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 20:13:29

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Amendment 2 (2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 20:13:29

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 20:13:29
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 20:13:29
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 20:13:29
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 20:13:29
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	RWS_ENDPOINT	21 Aug 2020 19:54:31
	ENDPOINT (b) (4)	
	(b) (4)	

US3042288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 20:13:32

US3042288

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 20:13:32
	(b) (4)	

US3042288

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:57:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:32

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
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)	22 Aug 2020 14:27:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 14:27:12
	(b) (4)	
Data point term sent to Coder	System	22 Aug 2020 14:25:56
Coding entries removed.	Rylea Gulick (b) (4)	22 Aug 2020 14:25:51
	(b) (4)	
User entered 'POST MENOPAUSAL' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Aug 2020 14:25:51
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 14:24:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 14:24:10
	(b) (4)	
Data point term sent to Coder	System	22 Aug 2020 14:23:52
User entered 'MENOPAUSE'	Rylea Gulick (b) (4)	22 Aug 2020 14:23:44
	(b) (4)	

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'UN UNK 2003'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:23:44
	(b) (4)	

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'Jan 2003'	(b) (4), (b) (6) System	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered '2003'	(b) (4), (b) (6) System	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered empty.	(b) (4), (b) (6) System	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered empty.	(b) (4), (b) (6) System	22 Aug 2020 14:23:44

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '14:36'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered '21 Aug 2020 14:36'	(b) (4), (b) (6) System	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '165.1' cm	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 20:13:32

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '106.2' kg	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 20:13:32

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
Amendment Manager: User entered '38.96102'	(b) (4), (b) (6)	
User entered '39.0'	System	17 Sep 2020 00:19:19
DataPoint set to visible.	System	22 Aug 2020 14:24:05
	System	21 Aug 2020 20:13:32

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'kg/m2'	(b) (4), (b) (6)	
	System	22 Aug 2020 14:24:05
DataPoint set to visible.	System	21 Aug 2020 20:13:32

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 07:38:37
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:48:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:48:11
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:45:21
User entered '37.0' C	Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:48:11
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:48:11
change Data Entry Error	(b) (4)	
User entered '90'	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'bpm'	(b) (4), (b) (6) System	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:48:11
change Data Entry Error	(b) (4)	
User entered '18'	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:48:11
change Data Entry Error	(b) (4)	
User entered '138'	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'mmHg'	(b) (4), (b) (6) System	22 Aug 2020 14:24:05

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:48:11
change Data Entry Error	(b) (4)	
User entered '82'	Rylea Gulick (b) (4)	22 Aug 2020 14:24:05
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User entered 'mmHg'	(b) (4), (b) (6) System	22 Aug 2020 14:24:05

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:15:31

US3042288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:15:31

US3042288

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:24:08

US3042288

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Aug 2020'	Rylea Gulick (b) (4)	22 Aug 2020 14:24:08
	(b) (4)	

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:25:07

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	22 Aug 2020 14:25:07
	(b) (4)	

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Aug 2020 14:25:37
	(b) (4)	
User entered 'Other (OTHER)'	Rylea Gulick (b) (4)	22 Aug 2020 14:25:07
	(b) (4)	

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	22 Aug 2020 14:25:37
	(b) (4)	
User entered 'MENOPAUSAL'	Rylea Gulick (b) (4)	22 Aug 2020 14:25:07
	(b) (4)	

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:25:07

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:25:07

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'UN UNK 2003' reason for change:	Rylea Gulick (b) (4)	22 Aug 2020 14:25:37
Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:25:07
	(b) (4)	

US3042288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:53

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:25:07
	(b) (4)	

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	22 Aug 2020 14:26:28
	(b) (4)	

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:26:28
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'PATIENT GOES OUT IN COMMUNITY WITHOUT A MASK'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:26:28
	(b) (4)	

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:28

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	22 Aug 2020 14:26:28
	(b) (4)	

US3042288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:15:31
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:26:28
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:26:39
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:39

US3042288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4)	22 Aug 2020 14:26:39
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'VISIT1'	(b) (4), (b) (6) System	22 Aug 2020 14:26:39

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 AUG 2020'	RWS_ENDPOINT	21 Aug 2020 19:54:40
	ENDPOINT (b) (4)	
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '187611'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 19:54:40

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 19:54:40

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:46

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:46

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:46

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:46

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:26:46

US3042288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:53

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 09:05:48
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:54:22
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 17:54:19
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:12:44
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:12:34

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:30:20
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	28 Oct 2020 19:52:32
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:52:29
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:23:15
User entered '165.1' cm	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:52:29
change Data Entry Error	(b) (4)	
User entered '106.2' kg	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:30:20
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	28 Oct 2020 19:52:32
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:52:29
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:23:15
User entered '165.1' cm	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:52:29
change Data Entry Error	(b) (4)	
User entered '106.2' kg	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '14:36'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered '21 Aug 2020 14:36'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '37.0' C	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '90'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'bpm'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '18'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '138'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'mmHg'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '82'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'mmHg'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:30:20
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	28 Oct 2020 19:52:32
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:52:29
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:23:15
User entered '165.1' cm	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:52:29
change Data Entry Error	(b) (4)	
User entered '106.2' kg	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '15:41'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered '21 Aug 2020 15:41'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '37.2' C	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '86'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'bpm'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '16'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '138'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

US3042288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'mmHg'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '88'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'mmHg'	(b) (4), (b) (6) System	22 Aug 2020 14:27:33

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:37

US3042288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 20:13:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 20:13:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 20:13:46

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 20:13:46

US3042288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '15:10'	Rylea Gulick (b) (4)	21 Aug 2020 20:13:46
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered '21 Aug 2020 15:10'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 20:13:46
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'ONCE'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:49

US3042288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:27:49

US3042288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '14:50'	Rylea Gulick (b) (4)	22 Aug 2020 14:27:49
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered '21 Aug 2020 14:50'	(b) (4), (b) (6) System	22 Aug 2020 14:27:49

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:28:04
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '14:42'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered '21 Aug 2020 14:42'	(b) (4), (b) (6) System	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4)	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 14:28:04
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered empty.	(b) (4), (b) (6) System	22 Aug 2020 14:28:04

US3042288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 14:28:06
	(b) (4)	

US3042288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:27
User entered '1'	(b) (4), (b) (6) System	22 Aug 2020 14:28:06

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:43:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '11222528-4228-452b-95ef-69102acf9db7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 20:44:17
	System	21 Aug 2020 20:44:17

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:43:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '11222528-4228-452b-95ef-69102acf9db7' User entered '99.0'	(b) (4), (b) (6) System	21 Aug 2020 20:44:17
	System	21 Aug 2020 20:44:17

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:43:55', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '11222528-4228-452b-95ef-69102acf9db7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 20:44:17

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:44:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '11222528-4228-452b-95ef-69102acf9db7' User entered '21 Aug 2020 15:44'	(b) (4), (b) (6) System	21 Aug 2020 20:44:17
	System	21 Aug 2020 20:44:17

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 15:30'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 18:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:44:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7baead16-09fa-4be9-9fcd-e58e4033efd5' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:14
	System	22 Aug 2020 23:30:14

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:44:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7baead16-09fa-4be9-9fcd-e58e4033efd5' User entered '96.7'	(b) (4), (b) (6) System	22 Aug 2020 23:30:14
	System	22 Aug 2020 23:30:14

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:44:40', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7baead16-09fa-4be9-9fcd-e58e4033efd5' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:14
	System	22 Aug 2020 23:30:14

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:45:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7baead16-09fa-4be9-9fcd-e58e4033efd5' User entered '21 Aug 2020 20:45'	(b) (4), (b) (6) System	22 Aug 2020 23:30:14
	System	22 Aug 2020 23:30:14

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 18:55'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 2'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:30:29', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f86150de-048d-4d79-9c5a-1ee0e32ec11d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:59
	System	22 Aug 2020 23:30:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:30:41', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f86150de-048d-4d79-9c5a-1ee0e32ec11d' User entered '98.4'	(b) (4), (b) (6) System	22 Aug 2020 23:30:59
	System	22 Aug 2020 23:30:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:30:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f86150de-048d-4d79-9c5a-1ee0e32ec11d' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:59
	System	22 Aug 2020 23:30:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:30:57', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f86150de-048d-4d79-9c5a-1ee0e32ec11d' User entered '22 Aug 2020 18:30'	(b) (4), (b) (6) System	22 Aug 2020 23:30:59
	System	22 Aug 2020 23:30:59

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 3'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:02:52', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '79a72f8b-6092-4424-a7bd-4e962f07402d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 23:03:28
	System	23 Aug 2020 23:03:28

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:05', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '79a72f8b-6092-4424-a7bd-4e962f07402d' User entered '98.6'	(b) (4), (b) (6) System	23 Aug 2020 23:03:28
	System	23 Aug 2020 23:03:28

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:11', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '79a72f8b-6092-4424-a7bd-4e962f07402d' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:03:28
	System	23 Aug 2020 23:03:28

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:26', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '79a72f8b-6092-4424-a7bd-4e962f07402d' User entered '23 Aug 2020 18:03'	(b) (4), (b) (6) System	23 Aug 2020 23:03:28
	System	23 Aug 2020 23:03:28

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 4'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:02:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0e7d3dec-65f7-4027-a6c4-fe16123eea51' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 23:03:03
	System	24 Aug 2020 23:03:03

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:02:34', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0e7d3dec-65f7-4027-a6c4-fe16123eea51' User entered '98.3'	(b) (4), (b) (6) System	24 Aug 2020 23:03:03
	System	24 Aug 2020 23:03:03

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:02:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0e7d3dec-65f7-4027-a6c4-fe16123eea51' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:03:03
	System	24 Aug 2020 23:03:03

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:02:59', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0e7d3dec-65f7-4027-a6c4-fe16123eea51' User entered '24 Aug 2020 18:02'	(b) (4), (b) (6) System	24 Aug 2020 23:03:03
	System	24 Aug 2020 23:03:03

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 5'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:26:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2e4247ae-9ffd-418f-a994-6d1ac495b0dd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:05
	System	26 Aug 2020 23:05:05

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:26:59', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2e4247ae-9ffd-418f-a994-6d1ac495b0dd' User entered '98.5'	(b) (4), (b) (6) System	26 Aug 2020 23:05:05
	System	26 Aug 2020 23:05:05

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:27:29', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2e4247ae-9ffd-418f-a994-6d1ac495b0dd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 23:05:05

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:27:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2e4247ae-9ffd-418f-a994-6d1ac495b0dd' User entered '25 Aug 2020 17:27'	(b) (4), (b) (6) System	26 Aug 2020 23:05:05
	System	26 Aug 2020 23:05:05

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 6'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:05:17', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'fd716bce-d218-4db6-b3d6-a6908e2eb01f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:49
	System	26 Aug 2020 23:05:49

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:05:29', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'fd716bce-d218-4db6-b3d6-a6908e2eb01f' User entered '97.8'	(b) (4), (b) (6) System	26 Aug 2020 23:05:49
	System	26 Aug 2020 23:05:49

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:05:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'fd716bce-d218-4db6-b3d6-a6908e2eb01f' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:49
	System	26 Aug 2020 23:05:49

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:05:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'fd716bce-d218-4db6-b3d6-a6908e2eb01f' User entered '26 Aug 2020 18:05'	(b) (4), (b) (6) System	26 Aug 2020 23:05:49
	System	26 Aug 2020 23:05:49

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 7'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:05:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b9e5290b-9da7-44c0-8e46-659c8c485f4c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:04', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b9e5290b-9da7-44c0-8e46-659c8c485f4c' User entered '98.5'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b9e5290b-9da7-44c0-8e46-659c8c485f4c' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b9e5290b-9da7-44c0-8e46-659c8c485f4c' User entered '27 Aug 2020 18:06'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:44:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbba62f0-b1e4-45b1-88bd-16b6e3cc9ba5' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 20:45:07
	System	21 Aug 2020 20:45:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:44:33', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbba62f0-b1e4-45b1-88bd-16b6e3cc9ba5' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:45:07
	System	21 Aug 2020 20:45:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:44:37', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbba62f0-b1e4-45b1-88bd-16b6e3cc9ba5' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:45:07
	System	21 Aug 2020 20:45:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:44:48', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbba62f0-b1e4-45b1-88bd-16b6e3cc9ba5' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 20:45:07
	System	21 Aug 2020 20:45:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:45:04', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbba62f0-b1e4-45b1-88bd-16b6e3cc9ba5' User entered '21 Aug 2020 15:45'	(b) (4), (b) (6) System	21 Aug 2020 20:45:07
	System	21 Aug 2020 20:45:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 15:30'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 18:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:45:26', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7123fbf4-f58b-47b0-8e6c-3f9942038d0d' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:15
	System	22 Aug 2020 23:30:15

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:45:37', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7123fbf4-f58b-47b0-8e6c-3f9942038d0d' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:15
	System	22 Aug 2020 23:30:15

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:45:49', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7123fbf4-f58b-47b0-8e6c-3f9942038d0d' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:15
	System	22 Aug 2020 23:30:15

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:46:02', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7123fbf4-f58b-47b0-8e6c-3f9942038d0d' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:15
	System	22 Aug 2020 23:30:15

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:46:25', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7123fbf4-f58b-47b0-8e6c-3f9942038d0d' User entered '21 Aug 2020 20:46'	(b) (4), (b) (6) System	22 Aug 2020 23:30:15
	System	22 Aug 2020 23:30:15

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 18:55'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 2'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:31:21', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '528de057-d910-431d-8fc4-a328cc4bb447'	(b) (4), (b) (6)	23 Aug 2020 23:02:29
User entered 'None (1)'	System	23 Aug 2020 23:02:29

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:31:25', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '528de057-d910-431d-8fc4-a328cc4bb447'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Aug 2020 23:02:29

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:31:30', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '528de057-d910-431d-8fc4-a328cc4bb447'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Aug 2020 23:02:29

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:31:41', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '528de057-d910-431d-8fc4-a328cc4bb447'	(b) (4), (b) (6)	23 Aug 2020 23:02:29
User entered 'None (1)'	System	23 Aug 2020 23:02:29

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:31:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '528de057-d910-431d-8fc4-a328cc4bb447' User entered '22 Aug 2020 18:31'	(b) (4), (b) (6) System	23 Aug 2020 23:02:29
	System	23 Aug 2020 23:02:29

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 3'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:38', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '57e0b452-0828-4359-8aff-74c543eaa0fd' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 23:04:08
	System	23 Aug 2020 23:04:08

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:43', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '57e0b452-0828-4359-8aff-74c543eaa0fd' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:04:08
	System	23 Aug 2020 23:04:08

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '57e0b452-0828-4359-8aff-74c543eaa0fd' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:04:08
	System	23 Aug 2020 23:04:08

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:03:56', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '57e0b452-0828-4359-8aff-74c543eaa0fd' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 23:04:08
	System	23 Aug 2020 23:04:08

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '57e0b452-0828-4359-8aff-74c543eaa0fd' User entered '23 Aug 2020 18:04'	(b) (4), (b) (6) System	23 Aug 2020 23:04:08
	System	23 Aug 2020 23:04:08

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 4'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:09', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0d3e4c9a-95c3-4a77-a402-d2a3cdbb7bb5' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 23:03:50
	System	24 Aug 2020 23:03:50

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0d3e4c9a-95c3-4a77-a402-d2a3cdbb7bb5' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:03:50
	System	24 Aug 2020 23:03:50

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:19', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0d3e4c9a-95c3-4a77-a402-d2a3cdbb7bb5' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:03:50
	System	24 Aug 2020 23:03:50

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:26', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0d3e4c9a-95c3-4a77-a402-d2a3cdbb7bb5' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 23:03:50
	System	24 Aug 2020 23:03:50

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0d3e4c9a-95c3-4a77-a402-d2a3cdbb7bb5' User entered '24 Aug 2020 18:03'	(b) (4), (b) (6) System	24 Aug 2020 23:03:50
	System	24 Aug 2020 23:03:50

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 5'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:27:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '4e43a924-3d69-4419-afe0-8347859dba62' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:27:59', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '4e43a924-3d69-4419-afe0-8347859dba62'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:28:08', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '4e43a924-3d69-4419-afe0-8347859dba62' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:28:21', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '4e43a924-3d69-4419-afe0-8347859dba62' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:28:36', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '4e43a924-3d69-4419-afe0-8347859dba62'	(b) (4), (b) (6)	
User entered '25 Aug 2020 17:28'	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 6'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:05:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b3a9c783-36ea-49dc-8596-b5e380313bdd' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 23:06:25
	System	26 Aug 2020 23:06:25

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:01', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b3a9c783-36ea-49dc-8596-b5e380313bdd' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 23:06:25
	System	26 Aug 2020 23:06:25

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b3a9c783-36ea-49dc-8596-b5e380313bdd' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 23:06:25
	System	26 Aug 2020 23:06:25

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:16', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b3a9c783-36ea-49dc-8596-b5e380313bdd' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 23:06:25
	System	26 Aug 2020 23:06:25

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b3a9c783-36ea-49dc-8596-b5e380313bdd' User entered '26 Aug 2020 18:06'	(b) (4), (b) (6) System	26 Aug 2020 23:06:25
	System	26 Aug 2020 23:06:25

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 7'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:25', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd9dace22-21bf-4d21-a58a-9178e65ba725'	(b) (4), (b) (6)	
User entered 'None (1)'	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:34', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd9dace22-21bf-4d21-a58a-9178e65ba725' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:38', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd9dace22-21bf-4d21-a58a-9178e65ba725' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd9dace22-21bf-4d21-a58a-9178e65ba725'	(b) (4), (b) (6)	
	System	21 Sep 2020 15:35:52
User entered 'None (1)'	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:06:55', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd9dace22-21bf-4d21-a58a-9178e65ba725' User entered '27 Aug 2020 18:06'	(b) (4), (b) (6) System	21 Sep 2020 15:35:52
	System	21 Sep 2020 15:35:52

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:45:31', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:45:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:45:49', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:45:55', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:46:02', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:46:07', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:46:15', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T15:46:21', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd8f5b05e-83d7-4a3a-98e1-3ba13b703654' User entered '21 Aug 2020 15:46'	(b) (4), (b) (6) System	21 Aug 2020 20:46:22
	System	21 Aug 2020 20:46:22

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 15:30'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 18:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:46:43', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:46:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:46:59', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:47:08', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:47:15', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:47:20', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:47:32', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-21T20:47:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2ce759e3-7bcd-4fe8-8a40-42be564035fa' User entered '21 Aug 2020 20:47'	(b) (4), (b) (6) System	22 Aug 2020 23:30:17
	System	22 Aug 2020 23:30:17

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Aug 2020 18:55'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 2'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:32:13', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:32:25', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:32:30', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:32:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:32:41', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:32:49', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:33:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-22T18:33:16', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1f67ef94-35dc-47a2-94f6-110d62d61e94' User entered '22 Aug 2020 18:33'	(b) (4), (b) (6) System	23 Aug 2020 23:02:31
	System	23 Aug 2020 23:02:31

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 3'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:22', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:38', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:04:58', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-23T18:05:21', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '87415aab-05fe-493f-ac5a-ffba10e7fef9' User entered '23 Aug 2020 18:05'	(b) (4), (b) (6) System	23 Aug 2020 23:05:23
	System	23 Aug 2020 23:05:23

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 4'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:03:57', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:04:06', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:04:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:04:19', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-24T18:04:32', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '67b04060-6a15-45e4-a619-6346ac75370a' User entered '24 Aug 2020 18:04'	(b) (4), (b) (6) System	24 Aug 2020 23:04:37
	System	24 Aug 2020 23:04:37

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 5'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:28:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:28:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:29:36', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:29:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:29:07', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:29:11', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:29:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-25T17:29:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '83c519a5-7e01-431a-8111-3af794b1653e' User entered '25 Aug 2020 17:29'	(b) (4), (b) (6) System	26 Aug 2020 23:05:07
	System	26 Aug 2020 23:05:07

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 6'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:32', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:42', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:06:58', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-26T18:07:21', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f3f77369-d8b8-492e-b2d7-a6630556c29a' User entered '26 Aug 2020 18:07'	(b) (4), (b) (6) System	26 Aug 2020 23:07:24
	System	26 Aug 2020 23:07:24

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 7'	System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:06', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:09', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:13', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:21', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-08-27T18:07:38', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '02223586-9f58-4508-acf1-c2edc441cb95' User entered '27 Aug 2020 18:07'	(b) (4), (b) (6) System	21 Sep 2020 15:35:53
	System	21 Sep 2020 15:35:53

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:21
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4)	05 Sep 2020 23:39:56

US3042288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:21
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '28 Aug 2020'	(b) (4) Jamie Thompson (b) (4)	05 Sep 2020 23:39:56

US3042288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:21
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4)	05 Sep 2020 23:39:56

US3042288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:21
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	Jamie Thompson (b) (4)	05 Sep 2020 23:39:56

US3042288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:21
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	05 Sep 2020 23:40:00

US3042288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:21
User entered 'I'	System	05 Sep 2020 23:40:00

US3042288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	05 Sep 2020 23:40:19

US3042288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '5 Sep 2020'	(b) (4) Jamie Thompson (b) (4)	05 Sep 2020 23:40:19
	(b) (4)	

US3042288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4)	05 Sep 2020 23:40:19

US3042288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	Jamie Thompson (b) (4)	05 Sep 2020 23:40:19

US3042288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	05 Sep 2020 23:40:23

US3042288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:05:25
User entered 'I'	System	05 Sep 2020 23:40:23

US3042288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:40:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 20:50:42
	(b) (4)	

US3042288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:40:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 20:50:42
	(b) (4)	

US3042288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:40:09
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Sep 2020 20:50:42

US3042288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:40:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 20:50:42
	(b) (4)	

US3042288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:40:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 20:50:44
	(b) (4)	

US3042288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:40:09
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 20:50:44

US3042288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:45:39
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:45:39
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	21 Sep 2020 15:45:39
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'VISIT2'	(b) (4), (b) (6) System	21 Sep 2020 15:45:39

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '09:15'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered '21 Sep 2020 09:15'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '36.6' C	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '83'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'bpm'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '140'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'mmHg'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '76'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'mmHg'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '10:33'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered '21 Sep 2020 10:33'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '36.9' C	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '76'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'bpm'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '132'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'mmHg'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '76'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:01
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'mmHg'	(b) (4), (b) (6) System	21 Sep 2020 15:47:01

US3042288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:04
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:04
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:05:56
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Sep 2020 15:05:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Sep 2020 15:05:56
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:05:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '10:00'	Rylea Gulick (b) (4)	21 Sep 2020 15:05:56
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered '21 Sep 2020 10:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	21 Sep 2020 15:05:56
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'ONCE'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:14
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:14
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '09:41'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:14
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered '21 Sep 2020 09:41'	(b) (4), (b) (6) System	21 Sep 2020 15:47:14

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '09:48'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered '21 Sep 2020 09:48'	(b) (4), (b) (6) System	21 Sep 2020 15:47:21

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Sep 2020 15:47:21
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered empty.	(b) (4), (b) (6) System	21 Sep 2020 15:47:21

US3042288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 15:47:23
	(b) (4)	

US3042288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:27
User entered '1'	(b) (4), (b) (6) System	21 Sep 2020 15:47:23

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:36:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '99090cd9-1fc6-447e-badd-9a87b8417cae' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Sep 2020 15:36:53
	System	21 Sep 2020 15:36:53

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:36:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '99090cd9-1fc6-447e-badd-9a87b8417cae' User entered '98.5'	(b) (4), (b) (6) System	21 Sep 2020 15:36:53
	System	21 Sep 2020 15:36:53

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:36:32', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '99090cd9-1fc6-447e-badd-9a87b8417cae' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:36:53
	System	21 Sep 2020 15:36:53

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:36:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '99090cd9-1fc6-447e-badd-9a87b8417cae' User entered '21 Sep 2020 10:36'	(b) (4), (b) (6) System	21 Sep 2020 15:36:53
	System	21 Sep 2020 15:36:53

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 10:20'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 12:50'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:17:17', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'eb4169ae-c4d1-46d3-8e91-68ea763cab42' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:17:30', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'eb4169ae-c4d1-46d3-8e91-68ea763cab42' User entered '97.9'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:17:37', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'eb4169ae-c4d1-46d3-8e91-68ea763cab42' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:17:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'eb4169ae-c4d1-46d3-8e91-68ea763cab42' User entered '21 Sep 2020 19:17'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 13:45'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 2'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:06:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ae67485c-4ddb-4440-bc06-e172ad583bf8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:26
	System	22 Sep 2020 23:08:26

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:06:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ae67485c-4ddb-4440-bc06-e172ad583bf8' User entered '98.1'	(b) (4), (b) (6) System	22 Sep 2020 23:08:26
	System	22 Sep 2020 23:08:26

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:06:51', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ae67485c-4ddb-4440-bc06-e172ad583bf8' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:26
	System	22 Sep 2020 23:08:26

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:07:04', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ae67485c-4ddb-4440-bc06-e172ad583bf8' User entered '22 Sep 2020 18:07'	(b) (4), (b) (6) System	22 Sep 2020 23:08:26
	System	22 Sep 2020 23:08:26

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 3'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:04:08', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8b421afa-2de7-4d7a-b439-4899787141a9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Sep 2020 23:05:07
	System	23 Sep 2020 23:05:07

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:04:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8b421afa-2de7-4d7a-b439-4899787141a9' User entered '98.5'	(b) (4), (b) (6) System	23 Sep 2020 23:05:07
	System	23 Sep 2020 23:05:07

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:03:26', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8b421afa-2de7-4d7a-b439-4899787141a9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 23:05:07

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:05:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8b421afa-2de7-4d7a-b439-4899787141a9' User entered '23 Sep 2020 18:05'	(b) (4), (b) (6) System	23 Sep 2020 23:05:07
	System	23 Sep 2020 23:05:07

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 4'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:04:06', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a67c2e15-f091-4e24-b4e4-df01cbd02ce9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 23:04:52
	System	24 Sep 2020 23:04:52

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:04:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a67c2e15-f091-4e24-b4e4-df01cbd02ce9' User entered '98.4'	(b) (4), (b) (6) System	24 Sep 2020 23:04:52
	System	24 Sep 2020 23:04:52

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:04:19', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a67c2e15-f091-4e24-b4e4-df01cbd02ce9' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:04:52
	System	24 Sep 2020 23:04:52

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:04:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a67c2e15-f091-4e24-b4e4-df01cbd02ce9' User entered '24 Sep 2020 18:04'	(b) (4), (b) (6) System	24 Sep 2020 23:04:52
	System	24 Sep 2020 23:04:52

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 5'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:15:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '44f4edfe-8da9-4181-8d9b-d396002d5a88' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 23:16:24
	System	25 Sep 2020 23:16:24

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:16:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '44f4edfe-8da9-4181-8d9b-d396002d5a88' User entered '98.0'	(b) (4), (b) (6) System	25 Sep 2020 23:16:24
	System	25 Sep 2020 23:16:24

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:16:08', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '44f4edfe-8da9-4181-8d9b-d396002d5a88'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Sep 2020 23:16:24

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:16:20', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '44f4edfe-8da9-4181-8d9b-d396002d5a88' User entered '25 Sep 2020 18:16'	(b) (4), (b) (6) System	25 Sep 2020 23:16:24
	System	25 Sep 2020 23:16:24

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 6'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:44:25', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '54966d06-2470-4940-96f7-569f3b9e7c61' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:54
	System	26 Sep 2020 23:44:54

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:44:37', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '54966d06-2470-4940-96f7-569f3b9e7c61' User entered '98.3'	(b) (4), (b) (6) System	26 Sep 2020 23:44:54
	System	26 Sep 2020 23:44:54

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:44:42', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '54966d06-2470-4940-96f7-569f3b9e7c61' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:54
	System	26 Sep 2020 23:44:54

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:44:52', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '54966d06-2470-4940-96f7-569f3b9e7c61' User entered '26 Sep 2020 18:44'	(b) (4), (b) (6) System	26 Sep 2020 23:44:54
	System	26 Sep 2020 23:44:54

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 7'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:56:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '63b6dc20-87df-46da-bcd8-2eb171a4b25e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 00:57:43
	System	28 Sep 2020 00:57:43

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:57:24', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '63b6dc20-87df-46da-bcd8-2eb171a4b25e' User entered '97.9'	(b) (4), (b) (6) System	28 Sep 2020 00:57:43
	System	28 Sep 2020 00:57:43

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:57:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '63b6dc20-87df-46da-bcd8-2eb171a4b25e' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:57:43
	System	28 Sep 2020 00:57:43

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:57:40', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '63b6dc20-87df-46da-bcd8-2eb171a4b25e' User entered '27 Sep 2020 19:57'	(b) (4), (b) (6) System	28 Sep 2020 00:57:43
	System	28 Sep 2020 00:57:43

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:37:17', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '286e6e1d-484e-467b-8637-9c73526cde68' User entered 'None (1)'	(b) (4), (b) (6) System	21 Sep 2020 15:37:57
	System	21 Sep 2020 15:37:57

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:37:34', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '286e6e1d-484e-467b-8637-9c73526cde68' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:37:57
	System	21 Sep 2020 15:37:57

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:37:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '286e6e1d-484e-467b-8637-9c73526cde68' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 15:37:57
	System	21 Sep 2020 15:37:57

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:37:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '286e6e1d-484e-467b-8637-9c73526cde68' User entered 'None (1)'	(b) (4), (b) (6) System	21 Sep 2020 15:37:57
	System	21 Sep 2020 15:37:57

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:37:55', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '286e6e1d-484e-467b-8637-9c73526cde68' User entered '21 Sep 2020 10:37'	(b) (4), (b) (6) System	21 Sep 2020 15:37:57
	System	21 Sep 2020 15:37:57

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 10:20'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 12:50'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:18:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2609b679-4de1-4236-b1de-147e888d3848'	(b) (4), (b) (6)	22 Sep 2020 23:06:39
User entered 'None (1)'	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:18:19', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2609b679-4de1-4236-b1de-147e888d3848'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:18:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2609b679-4de1-4236-b1de-147e888d3848' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:18:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2609b679-4de1-4236-b1de-147e888d3848'	(b) (4), (b) (6)	22 Sep 2020 23:06:39
User entered 'None (1)'	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:18:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '2609b679-4de1-4236-b1de-147e888d3848' User entered '21 Sep 2020 19:18'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 13:45'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 2'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:07:13', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9b289f01-1c72-483d-9c9c-048eb7e6ed3b' User entered 'None (1)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:27
	System	22 Sep 2020 23:08:27

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:07:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9b289f01-1c72-483d-9c9c-048eb7e6ed3b' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:27
	System	22 Sep 2020 23:08:27

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:07:38', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9b289f01-1c72-483d-9c9c-048eb7e6ed3b' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:27
	System	22 Sep 2020 23:08:27

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:07:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9b289f01-1c72-483d-9c9c-048eb7e6ed3b' User entered 'None (1)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:27
	System	22 Sep 2020 23:08:27

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:07:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9b289f01-1c72-483d-9c9c-048eb7e6ed3b' User entered '22 Sep 2020 18:07'	(b) (4), (b) (6) System	22 Sep 2020 23:08:27
	System	22 Sep 2020 23:08:27

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 3'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:05:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '26ea890f-25b2-4121-93f3-2326ace1dc14' User entered 'None (1)'	(b) (4), (b) (6) System	23 Sep 2020 23:06:39
	System	23 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:05:57', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '26ea890f-25b2-4121-93f3-2326ace1dc14' User entered 'No (N)'	(b) (4), (b) (6) System	23 Sep 2020 23:06:39
	System	23 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '26ea890f-25b2-4121-93f3-2326ace1dc14' User entered 'No (N)'	(b) (4), (b) (6) System	23 Sep 2020 23:06:39
	System	23 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '26ea890f-25b2-4121-93f3-2326ace1dc14' User entered 'None (1)'	(b) (4), (b) (6) System	23 Sep 2020 23:06:39
	System	23 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:31', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '26ea890f-25b2-4121-93f3-2326ace1dc14' User entered '23 Sep 2020 18:06'	(b) (4), (b) (6) System	23 Sep 2020 23:06:39
	System	23 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 4'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '56439a0a-b658-425f-8759-f246971d5e2f' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:04
	System	24 Sep 2020 23:06:04

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:16', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '56439a0a-b658-425f-8759-f246971d5e2f' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:04
	System	24 Sep 2020 23:06:04

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '56439a0a-b658-425f-8759-f246971d5e2f' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:04
	System	24 Sep 2020 23:06:04

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:31', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '56439a0a-b658-425f-8759-f246971d5e2f' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:04
	System	24 Sep 2020 23:06:04

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:41', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '56439a0a-b658-425f-8759-f246971d5e2f' User entered '24 Sep 2020 18:05'	(b) (4), (b) (6) System	24 Sep 2020 23:06:04
	System	24 Sep 2020 23:06:04

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 5'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:16:29', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f14462a4-55b4-47d8-a976-828a46883aeb' User entered 'None (1)'	(b) (4), (b) (6) System	25 Sep 2020 23:17:23
	System	25 Sep 2020 23:17:23

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:16:44', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f14462a4-55b4-47d8-a976-828a46883aeb' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 23:17:23
	System	25 Sep 2020 23:17:23

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:01', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f14462a4-55b4-47d8-a976-828a46883aeb' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 23:17:23
	System	25 Sep 2020 23:17:23

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:09', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f14462a4-55b4-47d8-a976-828a46883aeb' User entered 'None (1)'	(b) (4), (b) (6) System	25 Sep 2020 23:17:23
	System	25 Sep 2020 23:17:23

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f14462a4-55b4-47d8-a976-828a46883aeb' User entered '25 Sep 2020 18:17'	(b) (4), (b) (6) System	25 Sep 2020 23:17:23
	System	25 Sep 2020 23:17:23

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 6'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:11', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbfc2029-4ffe-4bb9-945e-b40244be263a' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:18
	System	26 Sep 2020 23:46:18

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:15', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbfc2029-4ffe-4bb9-945e-b40244be263a' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:18
	System	26 Sep 2020 23:46:18

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:20', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbfc2029-4ffe-4bb9-945e-b40244be263a' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:18
	System	26 Sep 2020 23:46:18

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbfc2029-4ffe-4bb9-945e-b40244be263a' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:18
	System	26 Sep 2020 23:46:18

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:37', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'dbfc2029-4ffe-4bb9-945e-b40244be263a' User entered '26 Sep 2020 18:45'	(b) (4), (b) (6) System	26 Sep 2020 23:46:18
	System	26 Sep 2020 23:46:18

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 7'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:57:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '5c2a47f0-3311-41f0-9ef8-ef875feb0ef6' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:10
	System	28 Sep 2020 00:58:10

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:57:51', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '5c2a47f0-3311-41f0-9ef8-ef875feb0ef6' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:10
	System	28 Sep 2020 00:58:10

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:57:55', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '5c2a47f0-3311-41f0-9ef8-ef875feb0ef6' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:10
	System	28 Sep 2020 00:58:10

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '5c2a47f0-3311-41f0-9ef8-ef875feb0ef6' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:10
	System	28 Sep 2020 00:58:10

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:07', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '5c2a47f0-3311-41f0-9ef8-ef875feb0ef6' User entered '27 Sep 2020 19:58'	(b) (4), (b) (6) System	28 Sep 2020 00:58:10
	System	28 Sep 2020 00:58:10

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:05', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:20', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:24', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:34', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T10:38:40', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '279cf9ae-6ad3-49dc-ab43-56f64fe88932' User entered '21 Sep 2020 10:38'	(b) (4), (b) (6) System	21 Sep 2020 15:38:42
	System	21 Sep 2020 15:38:42

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 10:20'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 12:50'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:02', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:07', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:22', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:26', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:36', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-21T19:19:49', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'aeb754f3-9696-472e-86c1-968d7cd0312b' User entered '21 Sep 2020 19:19'	(b) (4), (b) (6) System	22 Sep 2020 23:06:39
	System	22 Sep 2020 23:06:39

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '21 Sep 2020 13:45'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 2'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:03', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:06', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:17', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-22T18:08:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '1b019581-8ad2-4efa-8966-a54c04ba49a5' User entered '22 Sep 2020 18:08'	(b) (4), (b) (6) System	22 Sep 2020 23:08:41
	System	22 Sep 2020 23:08:41

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 3'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:49', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:06:58', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:07:02', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:07:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:07:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-23T18:07:43', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd41f0852-0542-491a-a4a1-1af5708f1305' User entered '23 Sep 2020 18:07'	(b) (4), (b) (6) System	23 Sep 2020 23:07:45
	System	23 Sep 2020 23:07:45

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 4'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:48', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:52', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:55', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:05:57', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:06:04', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-24T18:06:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ace8f1e9-5eb3-4535-aa1e-5f0825f8cea1' User entered '24 Sep 2020 18:06'	(b) (4), (b) (6) System	24 Sep 2020 23:06:15
	System	24 Sep 2020 23:06:15

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '24 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 5'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:31', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:38', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:43', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:17:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:18:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-25T18:18:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ee2797e3-782a-49ea-b5c3-2caab8e7abc3' User entered '25 Sep 2020 18:18'	(b) (4), (b) (6) System	26 Sep 2020 23:44:22
	System	26 Sep 2020 23:44:22

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 6'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:45:58', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:46:08', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:46:11', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:46:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:46:20', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-26T18:46:33', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '9a563876-8d14-4647-baaa-d279805275f8' User entered '26 Sep 2020 18:46'	(b) (4), (b) (6) System	26 Sep 2020 23:46:36
	System	26 Sep 2020 23:46:36

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Sep 2020 15:05:56
User entered 'Day 7'	System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:15', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:20', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:24', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:31', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:43', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-09-27T19:58:58', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '35926736-1a2a-45c4-bec2-4a18537c2a0e' User entered '27 Sep 2020 19:58'	(b) (4), (b) (6) System	28 Sep 2020 00:58:59
	System	28 Sep 2020 00:58:59

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	21 Sep 2020 15:05:56

US3042288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:29
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 18:35:55

US3042288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:29
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '28 Sep 2020'	Rylea Gulick (b) (4)	28 Sep 2020 18:35:55

US3042288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:29
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4)	28 Sep 2020 18:35:55

US3042288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:29
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered empty.	Rylea Gulick (b) (4)	28 Sep 2020 18:35:55

US3042288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:29
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Sep 2020 18:35:57

US3042288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:29
User entered 'I'	System	28 Sep 2020 18:35:57

US3042288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:39
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:21:39

US3042288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:39
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '05 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:21:39

US3042288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:39
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	05 Oct 2020 17:21:39

US3042288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:39
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	Rylea Gulick (b) (4)	05 Oct 2020 17:21:39

US3042288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:39
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:21:40

US3042288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:39
User entered 'I'	System	05 Oct 2020 17:21:40

US3042288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:00:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Oct 2020 17:19:20
	(b) (4)	

US3042288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:00:25
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '12 Oct 2020'	Rylea Gulick (b) (4)	12 Oct 2020 17:19:20
	(b) (4)	

US3042288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:00:25
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	12 Oct 2020 17:19:20
	(b) (4)	

US3042288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:00:25
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	12 Oct 2020 17:19:20
	(b) (4)	

US3042288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:00:25
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Oct 2020 17:19:22
	(b) (4)	

US3042288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:00:25
User entered 'I'	System	12 Oct 2020 17:19:22

US3042288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:01
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Oct 2020'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:01
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:01
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered 'VISIT3'	(b) (4), (b) (6) System	21 Oct 2020 16:29:01

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '21 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Oct 2020 16:29:25

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '09:00'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered '21 Oct 2020 09:00'	(b) (4), (b) (6) System	21 Oct 2020 16:29:25

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '36.6' C	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '77'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered 'bpm'	(b) (4), (b) (6) System	21 Oct 2020 16:29:25

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Oct 2020 16:29:25

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '140'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered 'mmHg'	(b) (4), (b) (6) System	21 Oct 2020 16:29:25

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '65'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:25
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered 'mmHg'	(b) (4), (b) (6) System	21 Oct 2020 16:29:25

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:37

US3042288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:37

US3042288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:29
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Oct 2020'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:29
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:38
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '21 Oct 2020'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:38
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '09:05'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:38
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered '21 Oct 2020 09:05'	(b) (4), (b) (6) System	21 Oct 2020 16:29:38

US3042288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Oct 2020 16:29:40
	(b) (4)	

US3042288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:37
User entered '1'	(b) (4), (b) (6) System	21 Oct 2020 16:29:40

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 64'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you been exposed to someone with 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)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:01:39
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 71'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-10-28T18:36:44', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a23b3e0b-36d7-4df8-8d42-3c861c853246' User entered 'No (N)'	(b) (4), (b) (6) System	05 Nov 2020 00:41:13
	System	05 Nov 2020 00:41:13

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-10-28T18:37:06', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a23b3e0b-36d7-4df8-8d42-3c861c853246' User entered 'No (N)'	(b) (4), (b) (6) System	05 Nov 2020 00:41:13
	System	05 Nov 2020 00:41:13

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-10-28T18:37:30', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'a23b3e0b-36d7-4df8-8d42-3c861c853246' User entered '28 Oct 2020 18:37:30'	(b) (4), (b) (6) System	05 Nov 2020 00:41:13
	System	05 Nov 2020 00:41:13

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 78'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-04T18:41:39', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '680d6432-f455-4619-b26c-31432ec50651' User entered 'No (N)'	(b) (4), (b) (6) System	12 Nov 2020 00:03:31
	System	12 Nov 2020 00:03:31

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-04T18:41:57', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '680d6432-f455-4619-b26c-31432ec50651'	(b) (4), (b) (6)	12 Nov 2020 00:03:31
User entered 'No (N)'	System	12 Nov 2020 00:03:31

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-04T18:42:19', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '680d6432-f455-4619-b26c-31432ec50651' User entered '04 Nov 2020 18:42:19'	(b) (4), (b) (6) System	12 Nov 2020 00:03:31
	System	12 Nov 2020 00:03:31

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered 'Day 92'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-18T06:34:36', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '21a59e16-5909-4b68-831b-334769fc48fb' User entered 'No (N)'	(b) (4), (b) (6) System	18 Nov 2020 12:35:06
	System	18 Nov 2020 12:35:06

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-18T06:34:47', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '21a59e16-5909-4b68-831b-334769fc48fb' User entered 'No (N)'	(b) (4), (b) (6) System	18 Nov 2020 12:35:06
	System	18 Nov 2020 12:35:06

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-18T06:35:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '21a59e16-5909-4b68-831b-334769fc48fb' User entered '18 Nov 2020 06:35:00'	(b) (4), (b) (6) System	18 Nov 2020 12:35:06
	System	18 Nov 2020 12:35:06

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 20:13:46

US3042288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:58:24
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 20:13:46
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 20:13:46

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-23T18:25:19', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f847975e-8b45-4e3b-adf5-6fe8c68ce456'	System	24 Nov 2020 00:26:34
User entered 'No (N)'	System	24 Nov 2020 00:26:34

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-23T18:25:32', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f847975e-8b45-4e3b-adf5-6fe8c68ce456'	System	24 Nov 2020 00:26:34
User entered 'Yes (Y)'	System	24 Nov 2020 00:26:34

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-23T18:25:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f847975e-8b45-4e3b-adf5-6fe8c68ce456'	System	24 Nov 2020 00:26:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 00:26:34

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-11-23T18:26:24', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f847975e-8b45-4e3b-adf5-6fe8c68ce456'	System	24 Nov 2020 00:26:34
User entered '23 Nov 2020 18:26:24'	System	24 Nov 2020 00:26:34

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:34:23', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd'	System	09 Dec 2020 15:36:08
User entered 'Yes (Y)'	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:34:32', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd' User entered 'Yes (Y)'	System	09 Dec 2020 15:36:08
	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:34:42', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd'	System	09 Dec 2020 15:36:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:34:50', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd' User entered 'No (N)'	System	09 Dec 2020 15:36:08
	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:35:02', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd' User entered 'Yes (Y)'	System	09 Dec 2020 15:36:08
	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:35:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd'	System	09 Dec 2020 15:36:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-09T09:35:56', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8fed1f3c-fa2e-4942-89ca-9adf41ce2edd' User entered '09 Dec 2020 09:35:56'	System	09 Dec 2020 15:36:08
	System	09 Dec 2020 15:36:08

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-13T21:04:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0fcc7dbd-eed3-4abc-a01e-05fe1ed7ff10'	System	14 Dec 2020 03:05:09
User entered 'No (N)'	System	14 Dec 2020 03:05:09

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-13T21:04:53', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0fcc7dbd-eed3-4abc-a01e-05fe1ed7ff10'	System	14 Dec 2020 03:05:09
User entered 'No (N)'	System	14 Dec 2020 03:05:09

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-13T21:05:07', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '0fcc7dbd-eed3-4abc-a01e-05fe1ed7ff10' User entered '13 Dec 2020 21:05:07'	System	14 Dec 2020 03:05:09
	System	14 Dec 2020 03:05:09

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-20T07:26:30', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ba08ab94-4d3b-492d-936b-e6a6cfa49719'	System	20 Dec 2020 13:27:41
User entered 'No (N)'	System	20 Dec 2020 13:27:41

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-20T07:26:43', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ba08ab94-4d3b-492d-936b-e6a6cfa49719'	System	20 Dec 2020 13:27:41
User entered 'Yes (Y)'	System	20 Dec 2020 13:27:41

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-20T07:26:56', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ba08ab94-4d3b-492d-936b-e6a6cfa49719'	System	20 Dec 2020 13:27:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 13:27:41

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-20T07:27:28', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'ba08ab94-4d3b-492d-936b-e6a6cfa49719' User entered '20 Dec 2020 07:27:28'	System	20 Dec 2020 13:27:41
	System	20 Dec 2020 13:27:41

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-28T08:15:04', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '95bc7707-77ae-4b2c-9662-9e4cf0a1c4ed'	System	28 Dec 2020 14:15:31
User entered 'No (N)'	System	28 Dec 2020 14:15:31

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-28T08:15:12', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '95bc7707-77ae-4b2c-9662-9e4cf0a1c4ed' User entered 'No (N)'	System	28 Dec 2020 14:15:31

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2020-12-28T08:15:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '95bc7707-77ae-4b2c-9662-9e4cf0a1c4ed' User entered '28 Dec 2020 08:15:27'	System	28 Dec 2020 14:15:31
	System	28 Dec 2020 14:15:31

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-04T07:01:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '935ff715-3909-493f-95d3-ed4db8904aef'	System	06 Jan 2021 15:32:53
User entered 'No (N)'	System	06 Jan 2021 15:32:53

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-04T07:01:18', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '935ff715-3909-493f-95d3-ed4db8904aef'	System	06 Jan 2021 15:32:53
User entered 'No (N)'	System	06 Jan 2021 15:32:53

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-04T07:01:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '935ff715-3909-493f-95d3-ed4db8904aef' User entered '04 Jan 2021 07:01:27'	System	06 Jan 2021 15:32:53
	System	06 Jan 2021 15:32:53

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-10T10:37:40', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd4f845d0-629f-496e-b0b0-381106c034f7' User entered 'No (N)'	System	16 Jan 2021 15:41:33
	System	16 Jan 2021 15:41:33

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-10T10:37:48', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd4f845d0-629f-496e-b0b0-381106c034f7' User entered 'No (N)'	System	16 Jan 2021 15:41:33
	System	16 Jan 2021 15:41:33

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-10T10:37:59', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd4f845d0-629f-496e-b0b0-381106c034f7' User entered '10 Jan 2021 10:37:59'	System	16 Jan 2021 15:41:33

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-17T18:30:35', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '3cc3a18a-e72a-4f54-94c9-fd87098536ac'	System	18 Jan 2021 00:31:07
User entered 'No (N)'	System	18 Jan 2021 00:31:07

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-17T18:30:46', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '3cc3a18a-e72a-4f54-94c9-fd87098536ac'	System	18 Jan 2021 00:31:07
User entered 'No (N)'	System	18 Jan 2021 00:31:07

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-17T18:31:04', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '3cc3a18a-e72a-4f54-94c9-fd87098536ac' User entered '17 Jan 2021 18:31:04'	System	18 Jan 2021 00:31:07

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-25T14:33:44', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '07795b95-b71f-469c-ba41-d50ee38a3d28' User entered 'No (N)'	System	25 Jan 2021 20:34:15
	System	25 Jan 2021 20:34:15

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-25T14:33:54', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '07795b95-b71f-469c-ba41-d50ee38a3d28' User entered 'No (N)'	System	25 Jan 2021 20:34:15
	System	25 Jan 2021 20:34:15

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-01-25T14:34:10', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '07795b95-b71f-469c-ba41-d50ee38a3d28' User entered '25 Jan 2021 14:34:10'	System	25 Jan 2021 20:34:15
	System	25 Jan 2021 20:34:15

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-01T10:37:14', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f9cc8f4d-8c7f-4f74-86c2-29bd90c078f6' User entered 'No (N)'	System	01 Feb 2021 16:37:38
	System	01 Feb 2021 16:37:38

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-01T10:37:24', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f9cc8f4d-8c7f-4f74-86c2-29bd90c078f6' User entered 'No (N)'	System	01 Feb 2021 16:37:38
	System	01 Feb 2021 16:37:38

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-01T10:37:34', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f9cc8f4d-8c7f-4f74-86c2-29bd90c078f6' User entered '01 Feb 2021 10:37:34'	System	01 Feb 2021 16:37:38
	System	01 Feb 2021 16:37:38

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-07T15:13:33', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8aeebc1b-32a1-49d4-92a2-e38cd3487ce2' User entered 'No (N)'	System	07 Feb 2021 21:13:51
	System	07 Feb 2021 21:13:51

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-07T15:13:41', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8aeebc1b-32a1-49d4-92a2-e38cd3487ce2'	System	07 Feb 2021 21:13:51
User entered 'No (N)'	System	07 Feb 2021 21:13:51

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-07T15:13:48', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8aeebc1b-32a1-49d4-92a2-e38cd3487ce2' User entered '07 Feb 2021 15:13:48'	System	07 Feb 2021 21:13:51
	System	07 Feb 2021 21:13:51

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-14T13:36:16', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f1d0a122-1304-4155-a596-bacff9fafae4' User entered 'No (N)'	System	14 Feb 2021 19:36:48
	System	14 Feb 2021 19:36:48

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-14T13:36:27', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f1d0a122-1304-4155-a596-bacff9fafae4' User entered 'No (N)'	System	14 Feb 2021 19:36:48
	System	14 Feb 2021 19:36:48

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-14T13:36:45', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'f1d0a122-1304-4155-a596-bacff9fafae4' User entered '14 Feb 2021 13:36:45'	System	14 Feb 2021 19:36:48
	System	14 Feb 2021 19:36:48

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-21T11:11:16', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd52a0121-4aee-46d7-86e3-67999658cccd' User entered 'No (N)'	System	24 Feb 2021 16:22:58
	System	24 Feb 2021 16:22:58

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-21T11:11:25', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd52a0121-4aee-46d7-86e3-67999658cccd' User entered 'No (N)'	System	24 Feb 2021 16:22:58
	System	24 Feb 2021 16:22:58

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-21T11:11:42', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd52a0121-4aee-46d7-86e3-67999658cccd' User entered '21 Feb 2021 11:11:42'	System	24 Feb 2021 16:22:58
	System	24 Feb 2021 16:22:58

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-28T05:31:23-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '6a9ccc26-9fd0-4212-a18c-3f2edbeb2c69'	System	28 Feb 2021 11:31:44
User entered 'No (N)'	System	28 Feb 2021 11:31:44

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-28T05:31:28-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '6a9ccc26-9fd0-4212-a18c-3f2edbeb2c69' User entered 'No (N)'	System	28 Feb 2021 11:31:44

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-02-28T05:31:37-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '6a9ccc26-9fd0-4212-a18c-3f2edbeeb2c69' User entered '28 Feb 2021 11:31:37'	System	28 Feb 2021 11:31:44
	System	28 Feb 2021 11:31:44

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-08T20:07:09-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b799dbc2-92b2-4ad5-b8e4-d97acf42cb26'	System	09 Mar 2021 02:19:20
User entered 'No (N)'	System	09 Mar 2021 02:19:20

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-08T20:07:19-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b799dbc2-92b2-4ad5-b8e4-d97acf42cb26'	System	09 Mar 2021 02:19:20
User entered 'No (N)'	System	09 Mar 2021 02:19:20

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-08T20:07:35-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'b799dbc2-92b2-4ad5-b8e4-d97acf42cb26'	System	09 Mar 2021 02:19:20
User entered '08 Mar 2021 20:07:35'	System	09 Mar 2021 02:19:20

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-14T07:14:43-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd2eb22fe-0ab7-4c08-922c-5e43e0a743e9'	System	14 Mar 2021 12:15:22
User entered 'No (N)'	System	14 Mar 2021 12:15:22

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-14T07:14:55-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd2eb22fe-0ab7-4c08-922c-5e43e0a743e9'	System	14 Mar 2021 12:15:22
User entered 'No (N)'	System	14 Mar 2021 12:15:22

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-14T07:15:00-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'd2eb22fe-0ab7-4c08-922c-5e43e0a743e9' User entered '14 Mar 2021 07:15:00'	System	14 Mar 2021 12:15:22
	System	14 Mar 2021 12:15:22

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-21T09:16:00-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c19a641c-c46d-466d-8552-b7a664b31a11'	System	27 Mar 2021 15:43:49
User entered 'No (N)'	System	27 Mar 2021 15:43:49

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-21T09:16:10-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c19a641c-c46d-466d-8552-b7a664b31a11'	System	27 Mar 2021 15:43:49
User entered 'No (N)'	System	27 Mar 2021 15:43:49

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-21T09:16:14-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c19a641c-c46d-466d-8552-b7a664b31a11'	System	27 Mar 2021 15:43:49
User entered '21 Mar 2021 09:16:14'	System	27 Mar 2021 15:43:49

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-28T21:42:02-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7a7cb9b7-7013-4482-a34e-b0d5995ce974'	System	29 Mar 2021 02:42:26
User entered 'No (N)'	System	29 Mar 2021 02:42:26

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-28T21:42:14-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7a7cb9b7-7013-4482-a34e-b0d5995ce974'	System	29 Mar 2021 02:42:26
User entered 'No (N)'	System	29 Mar 2021 02:42:26

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-28T21:42:23-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '7a7cb9b7-7013-4482-a34e-b0d5995ce974' User entered '28 Mar 2021 21:42:23'	System	29 Mar 2021 02:42:26
	System	29 Mar 2021 02:42:26

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-04T08:04:31-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8efa6be4-9e14-408f-897b-b2c445b6ee56'	System	11 Apr 2021 17:59:53
User entered 'No (N)'	System	11 Apr 2021 17:59:53

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-04T08:04:38-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8efa6be4-9e14-408f-897b-b2c445b6ee56'	System	11 Apr 2021 17:59:53
User entered 'No (N)'	System	11 Apr 2021 17:59:53

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-04T08:04:43-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '8efa6be4-9e14-408f-897b-b2c445b6ee56'	System	11 Apr 2021 17:59:53
User entered '04 Apr 2021 08:04:43'	System	11 Apr 2021 17:59:53

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-11T13:01:06-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c62141e5-ceda-40a0-9f06-8e9f0eaf4477'	System	18 Apr 2021 14:46:52
User entered 'No (N)'	System	18 Apr 2021 14:46:52

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-11T13:01:16-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c62141e5-ceda-40a0-9f06-8e9f0eaf4477'	System	18 Apr 2021 14:46:52
User entered 'No (N)'	System	18 Apr 2021 14:46:52

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-11T13:01:29-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c62141e5-ceda-40a0-9f06-8e9f0eaf4477'	System	18 Apr 2021 14:46:52
User entered '11 Apr 2021 13:01:29'	System	18 Apr 2021 14:46:52

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-18T09:46:57-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'da71f110-7046-4c28-9082-5527ae24174a'	System	18 Apr 2021 14:47:17
User entered 'No (N)'	System	18 Apr 2021 14:47:17

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-18T09:47:05-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'da71f110-7046-4c28-9082-5527ae24174a'	System	18 Apr 2021 14:47:17
User entered 'No (N)'	System	18 Apr 2021 14:47:17

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-18T09:47:15-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'da71f110-7046-4c28-9082-5527ae24174a' User entered '18 Apr 2021 09:47:15'	System	18 Apr 2021 14:47:17
	System	18 Apr 2021 14:47:17

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-26T01:30:54-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c1e9ff7c-8dc5-463b-ad86-4f34def9afbf'	System	26 Apr 2021 06:31:19
User entered 'No (N)'	System	26 Apr 2021 06:31:19

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-26T01:31:05-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c1e9ff7c-8dc5-463b-ad86-4f34def9afbf'	System	26 Apr 2021 06:31:19
User entered 'No (N)'	System	26 Apr 2021 06:31:19

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-04-26T01:31:15-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'c1e9ff7c-8dc5-463b-ad86-4f34def9afbf'	System	26 Apr 2021 06:31:19
User entered '26 Apr 2021 01:31:15'	System	26 Apr 2021 06:31:19

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-05-02T08:45:45-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '661d7b68-7fa0-41f7-b6ba-f67a4d4f9496'	System	02 May 2021 13:46:09
User entered 'No (N)'	System	02 May 2021 13:46:09

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Have you been exposed to someone with 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 (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-05-02T08:45:53-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '661d7b68-7fa0-41f7-b6ba-f67a4d4f9496'	System	02 May 2021 13:46:09
User entered 'No (N)'	System	02 May 2021 13:46:09

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-05-02T08:46:06-05:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: '661d7b68-7fa0-41f7-b6ba-f67a4d4f9496'	System	02 May 2021 13:46:09
User entered '02 May 2021 08:46:06'	System	02 May 2021 13:46:09

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:01:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:01:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:01:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:01:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:01:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 01:01:39

US3042288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:01:39
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 01:01:39

US3042288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:57:53

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)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-02T08:58:12-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'e6268203-0cd4-484f-bdd9-2b458ab70b26'	System	02 Mar 2021 14:58:55
User entered 'No (N)'	System	02 Mar 2021 14:58:55

US3042288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:57:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:56
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21982FDE-9D88-403E-8693-7AB88B9CFFA9)', Time: '2021-03-02T08:58:24-06:00', User OID: 'PatientReportedOutcome (US3042288)', ODM File OID: 'e6268203-0cd4-484f-bdd9-2b458ab70b26'	System	02 Mar 2021 14:58:55
User entered '02 Mar 2021 08:58:24'	System	02 Mar 2021 14:58:55

US3042288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:13:29

US3042288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:13:29

US3042288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:28
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:13:29

US3042288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:13:29

US3042288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:13:35

US3042288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:28
User entered 'I'	System	10 Dec 2020 20:13:35

US3042288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Jan 2021 16:54:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 16:54:02
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Jan 2021 16:52:46
User entered 'No (N)'	(b) (4), (b) (6)	18 Jan 2021 16:52:46

US3042288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4)	18 Jan 2021 16:54:02
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 16:52:46

US3042288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:52:46

US3042288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:00
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Patient in convalescent phase and is being contacted daily'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:52:46

US3042288

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:53:05

US3042288

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:00
User entered 'I'	System	18 Jan 2021 16:53:05

US3042288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:53
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 17:03:39

US3042288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 17:03:39

US3042288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Jan 2021 17:03:39

US3042288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 17:03:39

US3042288

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 17:03:46

US3042288

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:53
User entered 'I'	(b) (4), (b) (6) System	18 Jan 2021 17:03:46

US3042288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:08:13
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 15:13:32

US3042288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:08:13
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 15:13:32

US3042288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:08:13
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:13:32

US3042288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:08:13
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:13:32

US3042288

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:08:13
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 15:13:39

US3042288

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:08:13
User entered 'I'	System	15 Feb 2021 15:13:39

US3042288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:26

US3042288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '19 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:26

US3042288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:26

US3042288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered 'VISIT4'	(b) (4), (b) (6) System	19 Mar 2021 16:09:26

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:05:23

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:57:40

US3042288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:57:40

US3042288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:28

US3042288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:28

US3042288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:33

US3042288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '19 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:33

US3042288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '10:56'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:33

US3042288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered '19 Mar 2021 10:56'	(b) (4), (b) (6) System	19 Mar 2021 16:09:33

US3042288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 16:09:35

US3042288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:57:40
User entered 'I'	(b) (4), (b) (6) System	19 Mar 2021 16:09:35

US3042288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:31:09

US3042288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:31:09

US3042288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:31:09

US3042288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:31:09

US3042288

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:56

US3042288

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 16:30:56

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:19
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:17:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:19
User entered '10:28'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:17:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '30 Nov 2020 10:28'	(b) (4), (b) (6) System	30 Nov 2020 17:17:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:19
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:17:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:17:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
User entered 'Day 1 (Day 1)'	(b) (4) Rylea Gulick (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Per ETRTR, According to AE page, covid symptoms started on 27 Nov 2020. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:25:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:31
Query 'Per ETRTR, According to AE page, covid symptoms started on 27 Nov 2020. Please reconcile.' answered with '27NOV2020 IS CORRECT START DATE. SYMPTOM LOG WILL BE UPDATED, HOWEVER, THEY WILL NOT BE IN NUMERICAL ORDER AS EDC DOES NOT CHANGE IT.' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:42:45
User opened query 'Per ETRTR, According to AE page, covid symptoms started on 27 Nov 2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 23:20:39
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '93'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '37.0' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:05

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
User entered 'Day 2 (Day 2)'	(b) (4) Rylea Gulick (b) (4)	01 Dec 2020 19:31:50

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '93'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '99.3' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4)	08 Dec 2020 18:24:45

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '02 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:45

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
User entered 'Day 4 (Day 4)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '03 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:24:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
Data Entry Error	(b) (4)	
User entered 'Day 5 (Day 5)'	Rylea Gulick (b) (4)	08 Dec 2020 18:25:04
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '04 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:04

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
User entered 'Day 6 (Day 6)'	(b) (4) Rylea Gulick (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '05 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:12

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 10 (Day 10)' reason for change:	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '06 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:25:21

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 11 (Day 11)' reason for change:	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
Data Entry Error	(b) (4)	
User entered 'Day 8 (Day 8)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '07 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '94'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '98.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:06

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 12 (Day 12)' reason for change:	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '08 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '94'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:26:44

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:43:46
User entered 'Day 10 (Day 10)'	(b) (4) Rylea Gulick (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '09 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '93'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:15:43

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 14 (Day 14)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 11 (Day 11)'	Rylea Gulick (b) (4)	10 Dec 2020 21:50:52
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '10 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '96'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '96.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	10 Dec 2020 21:50:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 15 (Day 15)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 12 (Day 12)'	Rylea Gulick (b) (4)	11 Dec 2020 20:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '11 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '98.0' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:36:23

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 16 (Day 16)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 13 (Day 13)'	Rylea Gulick (b) (4)	14 Dec 2020 22:48:53
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '12 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:48:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
User entered 'Day 14 (Day 14)'	(b) (4) Rylea Gulick (b) (4)	14 Dec 2020 22:49:08
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '13 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
User entered 'Day 15 (Day 15)'	(b) (4) Rylea Gulick (b) (4)	14 Dec 2020 22:49:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '14 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 22:49:53

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 19 (Day 19)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 16 (Day 16)'	Rylea Gulick (b) (4)	15 Dec 2020 19:43:19
	(b) (4)	

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '15 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '96.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 19:43:19

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 20 (Day 20)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 17 (Day 17)'	Rylea Gulick (b) (4)	16 Dec 2020 20:09:38
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '16 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '96'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 30 Nov 2020 symptom log on log line 17. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:36:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:06:49
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 30 Nov 2020 symptom log on log line 17. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:32:48
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:31:53
User entered 'None (None)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:31:53
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 30 Nov 2020 symptom log on log line 17. 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 06:34:04
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:06:57
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:32:12
User entered 'None (None)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:32:12
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 20:09:38

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 21 (Day 21)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 18 (Day 18)'	Rylea Gulick (b) (4)	17 Dec 2020 17:03:51
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '17 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '96'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 17:03:51

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 22 (Day 22)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 19 (Day 19)'	Rylea Gulick (b) (4)	18 Dec 2020 16:08:08
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '18 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:08:08

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 23 (Day 23)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:14
Data Entry Error	(b) (4)	
User entered 'Day 20 (Day 20)'	Rylea Gulick (b) (4)	21 Dec 2020 17:09:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '19 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Form: Symptom Log (20)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:01

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 24 (Day 24)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:44:32
User entered 'Day 21 (Day 21)'	(b) (4) Rylea Gulick (b) (4)	21 Dec 2020 17:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '20 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:09:41

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 25 (Day 25)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	06 Jan 2021 17:44:32
User entered 'Day 22 (Day 22)'	(b) (4) Rylea Gulick (b) (4)	21 Dec 2020 17:10:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '21 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '94'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '98.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 17:10:13

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Day 26 (Day 26)' reason for change:	Rylea Gulick (b) (4)	06 Jan 2021 17:44:32
Data Entry Error	(b) (4)	
User entered 'Day 23 (Day 23)'	Rylea Gulick (b) (4)	22 Dec 2020 18:35:30
	(b) (4)	

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Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '22 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

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Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '%'	(b) (4), (b) (6) System	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '97.7' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:35:30

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 1 (Day 1)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '27 Nov 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 2 (Day 2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '28 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered '29 Nov 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

US3042288

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 14:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 17:43:14

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

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[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:57:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Form: COVID Diagnostic Test

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[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
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)	10 Dec 2020 04:54:29
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 'entered into Ae' (Site from System).	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:17
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	09 Dec 2020 20:16:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Folder: Covid-19 Assessment 30 Nov 2020

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 12:14:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '01DEC2020 SHIPMENT TRACKING: 923173282503.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 14:34:36
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:30:52
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:57:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:57:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:18:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User entered '1'	(b) (4), (b) (6)	
	System	09 Dec 2020 20:16:04
User entered '0'	System	30 Nov 2020 17:18:16

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User closed query 'Please verify this field and the following 2 fields as the answer provided doesn't meet the severity criteria requested (i.e. >/= 125 bpm)' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:11:47
Query 'Please verify this field and the following 2 fields as the answer provided doesn't meet the severity criteria requested (i.e. >/= 125 bpm)' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:56:35
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:55:41
User opened query 'Please verify this field and the following 2 fields as the answer provided doesn't meet the severity criteria requested (i.e. >/= 125 bpm)' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 01:54:11
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:43:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:55:41
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:43:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	30 Dec 2020 14:55:41
	(b) (4)	
User entered '77' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Dec 2020 18:43:04
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	09 Dec 2020 20:16:52
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:53

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)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Re-query: Please verify as symptom log notes first date of <= 93% was on 30Nov2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:37:52
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:20:24
Query 'Re-query: Please verify as symptom log notes first date of <= 93% was on 30Nov2020' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 16:27:43
User entered '30 Nov 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 16:27:39
User opened query 'Re-query: Please verify as symptom log notes first date of <= 93% was on 30Nov2020' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:12:49
User closed query 'Please verify as symptom log notes first date of <= 93% was on 30Nov2020' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:12:49
Query 'Please verify as symptom log notes first date of <= 93% was on 30Nov2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:56:39
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:55:41
User opened query 'Please verify as symptom log notes first date of <= 93% was on 30Nov2020' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 01:55:07
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:25:37
User closed query 'Re-query x2: Per symptom log end date should equal 09Dec2020. Please correct.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:32:55
Query 'Re-query x2: Per symptom log end date should equal 09Dec2020. Please correct.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:15:23
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:15:19
User entered '09 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:15:19
User opened query 'Re-query x2: Per symptom log end date should equal 09Dec2020. Please correct.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:37:49
User closed query 'Re-query: Please verify as symptom log shows last date of SpO2 <= 93% was on 09Dec2020' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:37:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:20:24
Query 'Re-query: Please verify as symptom log shows last date of SpO2 <= 93% was on 09Dec2020' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 16:27:47
User opened query 'Re-query: Please verify as symptom log shows last date of SpO2 <= 93% was on 09Dec2020' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:13:10
User closed query 'Please verify as symptom log shows last date of SpO2 <= 93% was on 09Dec2020' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:13:10
Query 'Please verify as symptom log shows last date of SpO2 <= 93% was on 09Dec2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:56:44
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:55:41
User opened query 'Please verify as symptom log shows last date of SpO2 <= 93% was on 09Dec2020' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 01:55:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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EAB) (1725)

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Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User closed query 'Please verify as symptom log notes lowest value was 93%' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:12:08
Query 'Please verify as symptom log notes lowest value was 93%' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:56:50
User entered '93' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:55:41
User opened query 'Please verify as symptom log notes lowest value was 93%' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 01:56:12
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Generated On: 09 Jun 2021 14:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Generated On: 09 Jun 2021 14:57:53

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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Generated On: 09 Jun 2021 14:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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Audit	User	Time (GMT)
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User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:44:16
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:44:16
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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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)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:01:32
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Dec 2020 17:01:32
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	09 Dec 2020 20:16:52
	(b) (4)	

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Folder: Covid-19 Assessment 30 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:20:24
User entered '05 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:01:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:16:52

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:57:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:21:29
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:35:10

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:12:17
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'ENTRY UPDATED.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:11:05
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:03:25
User entered '02 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:57:53

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:12:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'ENTRY UPDATED.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:11:10
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:03:44
User entered '04 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:12:38
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'ENTRY UPDATED.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:11:16
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:03:52
User entered '06 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:12:45
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'ENTRY UPDATED.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:11:21
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:04:00
User entered '08 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 28DEC2020 recorded for Convalescence Visit Day 28, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database, as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:25:02
Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 28DEC2020 recorded for Convalescence Visit Day 28, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database, as appropriate.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:34:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 28DEC2020 recorded for Convalescence Visit Day 28, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database, as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:07:59
User accepted default value 'Day 14 (Day 14)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:26
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered '13 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Dec 2020 14:10:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:57:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:34:29
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:51
User entered '28 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:34:29
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 20:14:14

US3042288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	30 Nov 2020 17:14:43
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:41
User entered '30 Nov 2020'	Rylea Gulick (b) (4)	30 Nov 2020 17:14:43
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:41
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	30 Nov 2020 17:14:43
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User entered 'SICKD1'	(b) (4), (b) (6) System	30 Nov 2020 17:14:43

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '30 Nov 2020'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '10:28'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User entered '30 Nov 2020 10:28'	(b) (4), (b) (6) System	30 Nov 2020 17:15:42

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '165.1' cm	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	
DataPoint set to visible.	System	30 Nov 2020 17:14:43

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '106.1' kg	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	
DataPoint set to visible.	System	30 Nov 2020 17:14:43

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '37.0' C	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered empty.	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '86'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User entered 'bpm'	(b) (4), (b) (6) System	30 Nov 2020 17:15:42

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '24'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User entered 'breaths/min'	(b) (4), (b) (6) System	30 Nov 2020 17:15:42

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '134'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User entered 'mmHg'	(b) (4), (b) (6) System	30 Nov 2020 17:15:42

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:16:50
User entered '70'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:42
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User entered 'mmHg'	(b) (4), (b) (6) System	30 Nov 2020 17:15:42

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:17:03

US3042288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:17:03

US3042288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:17:07
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:48
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:17:07
User entered '30 Nov 2020'	Rylea Gulick (b) (4)	30 Nov 2020 17:15:48
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:57:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:17:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	30 Nov 2020 17:16:20
	(b) (4)	

US3042288

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:34
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 30 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:25:45
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 30 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '01DEC2020 SHIPMENT TRACKING: 923173283793.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 16:57:05
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 30 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 03:59:27
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:16:20

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	28 Dec 2020 16:59:23
	(b) (4)	

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:01
User entered '28 Dec 2020'	Rylea Gulick (b) (4)	28 Dec 2020 16:59:23
	(b) (4)	

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:01
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:27 28 Dec 2020 16:59:27
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered empty.	System Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:23 28 Dec 2020 16:59:23

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User entered 'SICKD28'	(b) (4), (b) (6) System	28 Dec 2020 16:59:23

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '28 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '10:01'	Rylea Gulick (b) (4)	28 Dec 2020 16:59:46
	(b) (4)	

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User entered '28 Dec 2020 10:01'	(b) (4), (b) (6) System	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '165.1' cm	Rylea Gulick (b) (4)	28 Dec 2020 16:59:46
DataPoint set to visible.	(b) (4) System	28 Dec 2020 16:59:23

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '105.8' kg	Rylea Gulick (b) (4)	28 Dec 2020 16:59:46
DataPoint set to visible.	(b) (4) System	28 Dec 2020 16:59:23

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '36.6' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered empty.	Rylea Gulick (b) (4)	28 Dec 2020 16:59:46
	(b) (4)	

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '92'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User entered 'bpm'	(b) (4), (b) (6) System	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User entered 'breaths/min'	(b) (4), (b) (6) System	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User entered '136'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User entered 'mmHg'	(b) (4), (b) (6) System	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:09
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Dec 2020 16:59:50
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Dec 2020 16:59:50
User entered '84' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:50
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Dec 2020 16:59:46
User entered '8'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User entered 'mmHg'	(b) (4), (b) (6) System	28 Dec 2020 16:59:46

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:28:30

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:28:30

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:27
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	28 Dec 2020 16:59:54
	(b) (4)	

US3042288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:27
User entered '28 Dec 2020'	Rylea Gulick (b) (4)	28 Dec 2020 16:59:54
	(b) (4)	

US3042288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 14:57:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:22:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:00:22

US3042288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 14:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:30
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:22:34
User entered '28 Dec 2020'	Rylea Gulick (b) (4)	28 Dec 2020 17:00:22
	(b) (4)	

US3042288

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 18:56:11
	(b) (4)	

US3042288

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 18:56:11
	(b) (4)	

US3042288

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessica Knight (b) (4)	16 Jan 2021 18:56:11
	(b) (4)	

US3042288

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 18:56:11

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '0'	Jamie Thompson (b) (4)	12 Mar 2021 17:37:09
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:34:41

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jamie Thompson (b) (4)	12 Mar 2021 17:37:09
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:34:41

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:05:48
User entered 'Placebo (Placebo)'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:05:48
User entered 'Placebo (Placebo)'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 18:57:14
	(b) (4)	

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '1'	(b) (4), (b) (6) System	16 Jan 2021 18:57:14

US3042288

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'I'	(b) (4), (b) (6) System	16 Jan 2021 18:57:14

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User entered empty.	System	16 Jan 2021 19:01:45
DataPoint set to visible.	System	16 Jan 2021 18:57:14

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User entered empty.	System	16 Jan 2021 19:01:45
DataPoint set to visible.	System	16 Jan 2021 18:57:14

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '10:06'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '16 Jan 2021 10:06'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '36.8' C	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Oral (Oral)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '78'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'bpm'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '12'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '138'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'mmHg'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '76'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'mmHg'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User entered empty.	System	16 Jan 2021 19:01:45
DataPoint set to visible.	System	16 Jan 2021 18:57:14

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '10:53'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '16 Jan 2021 10:53'	(b) (4), (b) (6)	
	System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '36.9' C	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Oral (Oral)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '84'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'bpm'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '14'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '138'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'mmHg'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered '80'	Jessica Knight (b) (4)	16 Jan 2021 19:01:45
	(b) (4)	

US3042288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'mmHg'	(b) (4), (b) (6) System	16 Jan 2021 19:01:45

US3042288

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:01:56
	(b) (4)	

US3042288

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	16 Jan 2021 19:02:05
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Jan 2021 19:02:05
User entered '16 Jan 2021' reason for change: Data Entry Error	Jessica Knight (b) (4)	16 Jan 2021 19:02:05
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	16 Jan 2021 19:01:56
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Jan 2021 19:01:56
User entered '16 Oct 2021'	Jessica Knight (b) (4)	16 Jan 2021 19:01:56
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:03:35
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:03:35
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	16 Jan 2021 19:03:35
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	16 Jan 2021 19:03:35
DataPoint set to visible.	System	16 Jan 2021 18:57:14

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 19:03:35
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '10:22'	Jessica Knight (b) (4)	16 Jan 2021 19:03:35
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '16 Jan 2021 10:22'	(b) (4), (b) (6) System	16 Jan 2021 19:03:35

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jessica Knight (b) (4)	16 Jan 2021 19:03:35
	(b) (4)	

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'ONCE'	(b) (4), (b) (6) System	16 Jan 2021 19:03:35

US3042288

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	16 Jan 2021 19:03:35

US3042288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:03:54
	(b) (4)	

US3042288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 19:03:54
	(b) (4)	

US3042288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '09:49'	Jessica Knight (b) (4)	16 Jan 2021 19:03:54
	(b) (4)	

US3042288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '16 Jan 2021 09:49'	(b) (4), (b) (6)	16 Jan 2021 19:03:54
	System	

US3042288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:04:07
	(b) (4)	

US3042288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 19:04:07
	(b) (4)	

US3042288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '09:51'	Jessica Knight (b) (4)	16 Jan 2021 19:04:07
	(b) (4)	

US3042288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '16 Jan 2021 09:51'	(b) (4), (b) (6) System	16 Jan 2021 19:04:07

US3042288

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

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 19:04:12
	(b) (4)	

US3042288

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

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:18:33
User entered '1'	(b) (4), (b) (6) System	16 Jan 2021 19:04:12

US3042288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:13:14

US3042288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:13:14

US3042288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:13:14

US3042288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:13:14

US3042288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:13:19

US3042288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
User entered 'I'	(b) (4), (b) (6) System	26 Jan 2021 17:13:19

US3042288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:57
	(b) (4), (b) (6)	
User entered '1'	System	26 Jan 2021 17:13:19
DataPoint set to visible.	System	26 Jan 2021 17:13:19

US3042288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	12 Mar 2021 17:36:16
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 01:26:18
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'Will note out of window' (Site from System).	Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:36:56
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Mar 2021 17:36:16
User entered '5 Mar 2021'	Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:36:16

US3042288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Clinic (Clinic)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:36:16

US3042288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'OLD29'	(b) (4), (b) (6) System	12 Mar 2021 17:36:16

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Jamie Thompson (b) (4)	12 Mar 2021 17:38:07
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '5 Mar 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '11:05'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered '5 Mar 2021 11:05'	(b) (4), (b) (6) System	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '36.5' C	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Oral (Oral)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered empty.	Jamie Thompson (b) (4)	12 Mar 2021 17:38:07
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '75'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'bpm'	(b) (4), (b) (6) System	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '16'	Jamie Thompson (b) (4)	12 Mar 2021 17:38:07
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '122'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '78'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 17:38:07

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '5 Mar 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '11:53'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered '5 Mar 2021 11:53'	(b) (4), (b) (6) System	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '36.7' C	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Oral (Oral)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered empty.	Jamie Thompson (b) (4)	12 Mar 2021 17:38:53
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '78'	Jamie Thompson (b) (4)	12 Mar 2021 17:38:53
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'bpm'	(b) (4), (b) (6) System	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '12'	Jamie Thompson (b) (4)	12 Mar 2021 17:38:53
	(b) (4)	

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '110'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '78'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'mmHg'	(b) (4), (b) (6) System	12 Mar 2021 17:38:53

US3042288

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:39:19

US3042288

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '5 Mar 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:39:19

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered empty.	Jamie Thompson (b) (4)	12 Mar 2021 17:39:51
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	12 Mar 2021 17:39:51
DataPoint set to visible.	System	26 Jan 2021 17:13:19

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered '5 Mar 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered '11:15'	Jamie Thompson (b) (4)	12 Mar 2021 17:39:51
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered '5 Mar 2021 11:15'	(b) (4), (b) (6) System	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'ONCE'	(b) (4), (b) (6) System	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	12 Mar 2021 17:39:51

US3042288

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
	(b) (4)	
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	12 Mar 2021 17:06:22
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:42
User entered 'I'	(b) (4), (b) (6) System	12 Mar 2021 17:06:22

US3042288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:58
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	12 Mar 2021 17:06:36
	(b) (4)	

US3042288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:58
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered '12 Mar 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:06:36

US3042288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:58
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:06:36

US3042288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:58
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:55
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	12 Mar 2021 17:06:36

US3042288

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:58
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	12 Mar 2021 17:06:43
	(b) (4)	

US3042288

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:58
User entered 'I'	(b) (4), (b) (6) System	12 Mar 2021 17:06:43

US3042288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:02

US3042288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:50
User entered '02 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:02

US3042288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:02

US3042288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	02 Apr 2021 16:15:02

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered '02 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:50
User entered '10:36'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 10:36'	System	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered '36.8' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
User entered 'Oral (Oral)'	(b) (4) Rylea Gulickt (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:50
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered '132'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 16:15:14

US3042288

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:16:25

US3042288

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:50
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:16:25

US3042288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:16:32

US3042288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
User entered '02 Apr 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:16:32

US3042288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:40:50
User entered '10:46'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Apr 2021 16:16:32

US3042288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 10:46'	System	02 Apr 2021 16:16:32

US3042288

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:57:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:52
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:25:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	30 Nov 2020 17:19:22
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:09:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:08
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:13
User entered	System	07 Dec 2020 19:47:53
'USA-US052-2020-mRNA-1273-P301000025'		
User entered 'New'	(b) (4), (b) (6)	07 Dec 2020 19:47:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
Data point term sent to Coder	System	21 Dec 2020 14:32:17
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 14:32:13
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 14:32:13
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of Covid-19 diagnostic testing, severity assessment and symptom log from the event onset of 27 Nov 2020 to symptom resolution. ' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 13:28:12
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of Covid-19 diagnostic testing, severity assessment and symptom log from the event onset of 27 Nov 2020 to symptom resolution. ' answered with 'assessment tab has been done.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:22:10
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of Covid-19 diagnostic testing, severity assessment and symptom log from the event onset of 27 Nov 2020 to symptom resolution. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:32:12
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:18:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:18:02
Data point term sent to Coder	System	07 Dec 2020 19:16:46
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 19:16:27
User entered 'COVID-19' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 19:16:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 17:20:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 17:20:54
Data point term sent to Coder	System	30 Nov 2020 17:20:13
User entered 'SUSPECTED COVID-19'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	07 Jan 2021 13:51:48
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:48:12
User closed query 'Please verify as this doesn't match illness/COVID data entered. Verify if this should be updated to YES' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 21:25:54
Query 'Please verify as this doesn't match illness/COVID data entered. Verify if this should be updated to YES' answered with 'updated' (Site from CRA).	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:00:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:00:34
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:26:22
User opened query 'Please verify as this doesn't match illness/COVID data entered. Verify if this should be updated to YES' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:14:21
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:48:18
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:20
User entered '27 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

US3042288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:22
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:24
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:36:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:26
User entered '22 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Dec 2020 18:36:09
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 16:38:22
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)	14 Dec 2020 18:35:35
User entered empty.	System	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:48:18
Query 'PV Query: Since the subject was hospitalized for the event of symptomatic Covid-19, appropriate CTCAE grade should be grade 4 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:30:01
User opened query 'PV Query: Since the subject was hospitalized for the event of symptomatic Covid-19, appropriate CTCAE grade should be grade 4 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 13:35:40
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:58:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:58:08
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	04 Dec 2020 21:58:08
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 17:19:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 19:14:32
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:45
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

US3042288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:46
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 04:45:13
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admission date is present' (Site from System).	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 19:15:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Dec 2020 19:14:32
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 19:14:32
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:48:55
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	07 Dec 2020 19:14:32
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:01
User entered '05 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	07 Dec 2020 19:33:23
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:48:24
User closed query 'Per CDM: Please note that when "Requires inpatient or prolongation of existing Hospitalization" is checked the "Admitted to ICU?" field should also be completed. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:04:39
Query 'Per CDM: Please note that when "Requires inpatient or prolongation of existing Hospitalization" is checked the "Admitted to ICU?" field should also be completed. Kindly update accordingly. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 21:29:15
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 21:29:11
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 21:29:11
User opened query 'Per CDM: Please note that when "Requires inpatient or prolongation of existing Hospitalization" is checked the "Admitted to ICU?" field should also be completed. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 11:09:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:49:02
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

US3042288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:10
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:08
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:15
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:58:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:58:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	04 Dec 2020 21:58:08
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 17:19:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:58:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:58:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	04 Dec 2020 21:58:08
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 17:19:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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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.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:18
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:20
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:35
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:33
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:36:09
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)	22 Dec 2020 17:32:25
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 'entry will be updated when available.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 14:03:34
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 13:25:05
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)	15 Dec 2020 13:28:17
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 'outcome will be put when available.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:27:06
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:34:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:34:23
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)	14 Dec 2020 18:33:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:49:30
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:48:34
User closed query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, and possible diastolic heart failure. (These diagnoses were indicated in the discharge summary as the subject's problems during the hospitalization). ? ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:10:01
Query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, and possible diastolic heart failure. (These diagnoses were indicated in the discharge summary as the subject's problems during the hospitalization). ? ' answered with 'ACUTE HYPOXEMIC RESPIRATORY FAILURE AND POSSIBLE DIASTOLIC HEART FAILURE IS NOT NECESSARY AS IT MAY BE CAUSED BY COVID-19.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 21:39:25
User opened query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, and possible diastolic heart failure. (These diagnoses were indicated in the discharge summary as the subject's problems during the hospitalization). ? ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:13:14
Query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, and possible diastolic heart failure. (These diagnosis were indicated in the discharge summary as the subject's problems during the hospitalization).' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:10:05
User opened query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, and possible diastolic heart failure. (These diagnosis were indicated in the discharge summary as the subject's problems during the hospitalization).' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:04:56

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, new diagnosis diabetes mellitus type 2, and possible diastolic heart failure. (These diagnosis were indicated in the discharge summary as the subject's problems during the hospitalization). ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:55:15
Query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, new diagnosis diabetes mellitus type 2, and possible diastolic heart failure. (These diagnosis were indicated in the discharge summary as the subject's problems during the hospitalization). ' answered with 'Will have PI evaluate' (Site from Safety).	Jamie Thompson (b) (4)	02 Mar 2021 16:01:49
User closed query 'PV Query: Please provide any symptoms experienced by the subject 27 Nov 2020 through 29 Nov 2020 and add to COVID-19 symptom log. If symptoms were not assessed during these dates, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:17:54
User closed query 'PV Query: It was reported that the subject tested positive for COVID-19 on 27 Nov 2020 and 30 Nov 2020. Please confirm if the subject had 2 separate tests performed. ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:17:51
Query 'PV Query: It was reported that the subject tested positive for COVID-19 on 27 Nov 2020 and 30 Nov 2020. Please confirm if the subject had 2 separate tests performed. ' answered with 'SUBJECT ONLY HAD ONE TEST PREFORMED' (Site from Safety).	Rylea Gulick (b) (4)	30 Dec 2020 14:58:25
Query 'PV Query: Please provide any symptoms experienced by the subject 27 Nov 2020 through 29 Nov 2020 and add to COVID-19 symptom log. If symptoms were not assessed during these dates, please state so. ' answered with 'SYMPTOMS WERE NOT ASSESSED.' (Site from Safety).	Rylea Gulick (b) (4)	30 Dec 2020 14:57:44
User opened query 'PV Query: Please provide any symptoms experienced by the subject 27 Nov 2020 through 29 Nov 2020 and add to COVID-19 symptom log. If symptoms were not assessed during these dates, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:29:16

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EAB) (1725)

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject tested positive for COVID-19 on 27 Nov 2020 and 30 Nov 2020. Please confirm if the subject had 2 separate tests performed. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:29:00
User closed query 'PV Query: The start date of the event is 27 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 27 Nov 2020 to the COVID-19 assessment symptom log in EDC. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 22:01:09
Query 'PV Query: The start date of the event is 27 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 27 Nov 2020 to the COVID-19 assessment symptom log in EDC. ' answered with 'subject tested positive at urgent care on 27nov2020' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 18:36:49
User closed query 'PV Query: Per protocol section 8.1.1; if the subject has at least two systemic symptoms or one respiratory symptom along with a positive SARS-CoV-2 by RT-PCR, then this must be filed as an event through the end of the study. Please reassess if COVID-19 meets criteria for reporting. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:32:20
User opened query 'PV Query: Please consider reporting the event of acute hypoxemic respiratory failure, COVID-19 viral infection with pneumonia, new diagnosis diabetes mellitus type 2, and possible diastolic heart failure. (These diagnosis were indicated in the discharge summary as the subject's problems during the hospitalization). ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 13:24:43
User opened query 'PV Query: The start date of the event is 27 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 27 Nov 2020 to the COVID-19 assessment symptom log in EDC. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 13:24:18
Query 'PV Query: Per protocol section 8.1.1; if the subject has at least two systemic symptoms or one respiratory symptom along with a positive SARS-CoV-2 by RT-PCR, then this must be filed as an event through the end of the study. Please reassess if COVID-19 meets criteria for reporting. ' answered with 'entry updated' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	21 Dec 2020 14:32:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:57:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Records sent via email; please let us know if you need any further documents. ' (Site from Safety).	Jamie Thompson (b) (4)	15 Dec 2020 21:38:36
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of Covid-19 diagnostic testing, severity assessment and symptom log from the event onset of 27 Nov 2020 to symptom resolution. ' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 13:28:19
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of Covid-19 diagnostic testing, severity assessment and symptom log from the event onset of 27 Nov 2020 to symptom resolution. ' answered with 'assessment tab has been done.' (Site from Safety).	Rylea Gulick (b) (4)	14 Dec 2020 20:23:08
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:34:59
User opened query 'PV Query: Per protocol section 8.1.1; if the subject has at least two systemic symptoms or one respiratory symptom along with a positive SARS-CoV-2 by RT-PCR, then this must be filed as an event through the end of the study. Please reassess if COVID-19 meets criteria for reporting. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:33:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of Covid-19 diagnostic testing, severity assessment and symptom log from the event onset of 27 Nov 2020 to symptom resolution. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 18:32:30
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Dec 2020 19:16:03
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 19:16:03
User entered 'SUBJECT WAS REFERRED TO MERCY ER AS O2 STAT WAS LOW. SUBJECT WAS THEN ADMITTED.' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 19:16:03
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Dec 2020 19:14:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:55

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Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 19:14:32
User entered '0'	System	30 Nov 2020 17:19:55

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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 '1'	System	07 Jan 2021 13:51:48
User entered '0'	System	30 Nov 2020 17:19:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Mar 2021 21:29:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:16:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:16:46
Data point term sent to Coder	System	22 Dec 2020 20:15:51
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '01 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Form: Adverse Events (2)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 20:15:42

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 20:15:42

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 17:03:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 17:03:03
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:03:03
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:15:42
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 17:03:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 17:03:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:03:03
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:15:42
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 17:03:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 17:03:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:03:03
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:15:42
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 20:15:42

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:38:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:38:00
Data point term sent to Coder	System	17 Feb 2021 16:37:08
User entered 'HYPERCHOLESTEROLEMIA'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '27 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 21:27:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Mar 2021 21:27:32
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulickt (b) (4) (b) (4)	19 Mar 2021 21:27:32
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 16:36:22
User entered empty.	Rylea Gulickt (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

Death

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 21:27:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Mar 2021 21:27:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 21:27:32
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 16:36:22
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 21:27:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Mar 2021 21:27:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 21:27:32
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 16:36:22
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

None

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 16:36:22

US3042288

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 16:36:22

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:57:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:52
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	05 Oct 2020 17:21:52
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:28:13

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:44
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
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 Oct 2020 17:23:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:23:21
Data point term sent to Coder	System	05 Oct 2020 17:22:40
User entered 'INFLUENZA VACCINATION'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:46
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'INFLUENZA PROPHYLAXIS'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:48
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '.5'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:54
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mL (mL)'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:58
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once (ONCE)'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:59
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:07
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:08
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '30 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:10
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:11
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:12
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '30 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:51:14
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User entered empty.	(b) (4), (b) (6) System	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User entered empty.	(b) (4), (b) (6) System	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:40
User entered empty.	(b) (4), (b) (6) System	05 Oct 2020 17:22:31

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Nov 2020 17:20:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Nov 2020 17:20:06
Data point term sent to Coder	System	30 Nov 2020 17:19:11
User entered 'ACETAMINOPHEN'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'SUSPECTED COVID-19'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '500'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '27 Nov 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:34:31
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:04:27
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:04:21
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:04:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:22:52
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:04:21
User entered '22 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 16:04:21
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User entered empty.	(b) (4), (b) (6) System	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User entered empty.	(b) (4), (b) (6) System	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:46
User entered empty.	(b) (4), (b) (6) System	30 Nov 2020 17:19:06

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:08:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:08:05
Data point term sent to Coder	System	08 Dec 2020 18:29:37
User entered 'ENOXAPARIN'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:21:57
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'THIS IS THE CORRECT INDICATION' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:22:37
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:13:36
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '40'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '06 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User closed query 'Per CDM, DM CLR re-query: Response noted. Please update to provide a stop date or provide explanation for the continued use of the medication.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:24:45
Query 'Per CDM, DM CLR re-query: Response noted. Please update to provide a stop date or provide explanation for the continued use of the medication.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:37
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:28
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:28
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:11:05
User opened query 'Per CDM, DM CLR re-query: Response noted. Please update to provide a stop date or provide explanation for the continued use of the medication.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:11:03
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'WILL BE REVIEWED AND UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:23:46
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:13:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:28
User entered '18 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:28
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:51
User entered '804 (804)'	(b) (4), (b) (6) System	08 Dec 2020 18:29:00

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDs, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:30:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:30:43
Data point term sent to Coder	System	08 Dec 2020 18:29:39
User entered 'DEXAMETHASONE'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:23:27
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'THIS IS THE CORRECT INDICATION' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:22:46
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:14:05
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '6' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	22 Dec 2020 18:52:39
User entered '2'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '06 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User closed query 'Per CDM, DM CLR re-query: Response noted. Please update to provide a stop date or provide explanation for the continued use of the medication.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:24:52
Query 'Per CDM, DM CLR re-query: Response noted. Please update to provide a stop date or provide explanation for the continued use of the medication.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:51
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:47
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:12:38
User opened query 'Per CDM, DM CLR re-query: Response noted. Please update to provide a stop date or provide explanation for the continued use of the medication.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:12:36
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'WILL BE REVIEWED AND UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:23:56
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:14:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:47
User entered '18 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 17:05:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:55
User entered '804 (804)'	(b) (4), (b) (6) System	08 Dec 2020 18:29:21

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:02:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:02:55
Data point term sent to Coder	System	08 Dec 2020 18:30:39
User entered 'FUROSEMIDE'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:25:03
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'THIS IS THE CORRECT INDICATION' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:22:54
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:14:39
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '20'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:35:56
User entered '06 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:35:56
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '06 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:35:56
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:59
User entered '804 (804)'	(b) (4), (b) (6) System	08 Dec 2020 18:29:47

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 23:38:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 23:38:17
Data point term sent to Coder	System	22 Dec 2020 20:37:16
User entered 'LASIX'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '40'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #5 FUROSEMIDE (01 DEC 2020-06 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Jan 2021 10:50:49
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #5 FUROSEMIDE (01 DEC 2020-06 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'THIS IS THE CORRECT STATE DATE FOR MEDICATION' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:23:12
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #5 FUROSEMIDE (01 DEC 2020-06 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:21:46
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '18 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:21:46
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:03
User entered '804 (804)'	(b) (4), (b) (6) System	22 Dec 2020 20:36:24

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:04:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:04:55
Data point term sent to Coder	System	22 Dec 2020 20:37:16
User entered 'ASCORBIC ACID'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '500'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:21:56
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '18 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:21:56
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:08
User entered '804 (804)'	(b) (4), (b) (6) System	22 Dec 2020 20:36:44

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: COLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:37:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:37:49
Data point term sent to Coder	System	22 Dec 2020 20:37:17
User entered 'COLECALCIFEROL'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '1000'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'IU (IU)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:04
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '18 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:13
User entered '804 (804)'	(b) (4), (b) (6) System	22 Dec 2020 20:37:11

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:39:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:39:14
Data point term sent to Coder	System	22 Dec 2020 20:38:18
User entered 'ZINC SULFATE'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '220'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:14
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '18 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:14
User entered empty.	Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User entered '1'	(b) (4), (b) (6) System	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:19
User entered '804 (804)'	(b) (4), (b) (6) System	22 Dec 2020 20:37:32

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 17:24:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 17:24:21
Data point term sent to Coder	System	28 Dec 2020 17:23:25
User entered 'REMDESIVIR'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '200'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'once (ONCE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Intravenous (INTRAVENOUS)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '01 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User entered empty.	(b) (4), (b) (6) System	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User entered empty.	(b) (4), (b) (6) System	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:09:31
User entered empty.	(b) (4), (b) (6) System	28 Dec 2020 17:22:50

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 17:25:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 17:25:22
Data point term sent to Coder	System	28 Dec 2020 17:24:26
User entered 'REMDESIVIR'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'COVID-19'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'other (OTHER)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Q24HOURS'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'Intravenous (INTRAVENOUS)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '02 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered '05 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:50:26
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User entered empty.	(b) (4), (b) (6) System	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User entered empty.	(b) (4), (b) (6) System	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:08:34
User entered empty.	(b) (4), (b) (6) System	28 Dec 2020 17:23:28

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:39:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 16:39:00
Data point term sent to Coder	System	17 Feb 2021 16:38:08
User entered 'ATORVASTATIN'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'HYPERCHOLESTEREMIA'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered '20'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered '27 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:51
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 16:37:23

US3042288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:57:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:40:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:09:20
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 14:09:10

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:14
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:25
	(b) (4), (b) (6)	12 Mar 2021 18:37:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	20 Apr 2021 14:49:48
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	15 Mar 2021 21:24:22
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:37:19
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:14
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 22:13:54
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
	(b) (4)	
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
	(b) (4)	
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
	(b) (4), (b) (6)	
User entered 'Miller'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:22
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '07/Dec/2020 19:48'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:14
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
	(b) (4)	
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
	(b) (4)	
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
	(b) (4), (b) (6)	
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:22
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '15/Dec/2020 08:33'	System	15 Dec 2020 13:33:28

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 14:58:36
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 13:33:28

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:14
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
	(b) (4)	
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
	(b) (4)	
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
	(b) (4)	
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:22
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '16/Dec/2020 09:58'	System	16 Dec 2020 14:58:52

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 14:58:52

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

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Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:14
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:25
	(b) (4), (b) (6)	12 Mar 2021 18:37:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	20 Apr 2021 14:49:48
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	15 Mar 2021 21:24:22
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '22/Dec/2020 12:32'	System	22 Dec 2020 17:32:45

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 17:32:52
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 17:32:45

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:14
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
	(b) (4)	
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
	(b) (4)	
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
	(b) (4), (b) (6)	
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	20 Apr 2021 14:49:48
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	15 Mar 2021 21:24:22
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '22/Dec/2020 22:01'	System	22 Dec 2020 22:01:50

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:53

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.	David Ensz (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:24:04
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 22:01:50

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:14
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
	(b) (4)	
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
	(b) (4)	
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
	(b) (4)	
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	20 Apr 2021 14:49:48
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	15 Mar 2021 21:24:22
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '04/Jan/2021 12:24'	System	04 Jan 2021 17:24:22

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:25:33
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 17:24:22

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:14
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:25
	(b) (4), (b) (6)	12 Mar 2021 18:37:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Miller'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:22
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered '07/Jan/2021 13:25'	System	07 Jan 2021 18:25:42

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:55:43
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 18:25:42

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:14
	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:25
	(b) (4), (b) (6)	12 Mar 2021 18:37:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
DataPoint Un-verified.	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Miller'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	20 Apr 2021 14:49:48
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	15 Mar 2021 21:24:22
	(b) (4)	
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:10:56
User entered '03/Mar/2021 10:55'	System	03 Mar 2021 16:56:00

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:10:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 16:56:00

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:19
	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:14
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:25
	(b) (4), (b) (6)	12 Mar 2021 18:37:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Miller'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:22
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:10:56
User entered '22/Mar/2021 13:23'	System	22 Mar 2021 13:23:21

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:57:53

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.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:10:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 13:23:21

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'USA-US052-2020-MRNA-1273-P301000025'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

US3042288

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Yes (Y)'	System	07 Dec 2020 19:47:53

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Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'No (N)'	System	07 Dec 2020 19:47:53

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:37:19
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:29
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:25
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 00:23:25
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:14
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Meagan'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 22:13:54
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	16 Dec 2020 22:13:54
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Meagan'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
	(b) (4)	
User closed query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:25
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:37:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:55:43
Query 'Please update to PI's name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	28 Jan 2021 00:23:34
Un-reviewed for Safety.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
DataPoint Un-verified.	(b) (4)	
	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 00:23:25
	(b) (4)	
User opened query 'Please update to PI's name' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:24:40
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 20:24:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 22:01:30
User entered 'Miller'	System	22 Dec 2020 17:32:45
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Dec 2020 22:13:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'Miller'	System	07 Dec 2020 19:47:53

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:54
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:54:52
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:59:51
User closed query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:08:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
Query 'Please add address' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:22
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
User opened query 'Please add address' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:37:55
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '330 dakota dunes suite400'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:57
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'North sioux'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:55:00
Un-reviewed for Safety.	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Apr 2021 14:49:34
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:24:17
	(b) (4)	
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered 'IA'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:55:02
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:35:19
Un-reviewed for Safety.	System	22 Mar 2021 13:23:21
User entered empty.	System	22 Mar 2021 13:23:21
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:22:50
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:24:17
Un-reviewed for Safety.	System	03 Mar 2021 16:56:00
DataPoint Un-verified.	System	03 Mar 2021 16:56:00
User entered empty.	System	03 Mar 2021 16:56:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 19:48:31
User entered '57049'	System	07 Dec 2020 19:47:53

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:23:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:33:20
User entered 'US'	System	07 Dec 2020 19:48:38

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Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	22 Mar 2021 13:23:21
User entered '8'	System	03 Mar 2021 16:56:00
User entered '7'	System	07 Jan 2021 18:25:42
User entered '6'	System	04 Jan 2021 17:24:22
User entered '5'	System	22 Dec 2020 22:01:50
User entered '4'	System	22 Dec 2020 17:32:45
User entered '3'	System	16 Dec 2020 14:58:52
User entered '2'	System	15 Dec 2020 13:33:28
User entered '1'	System	07 Dec 2020 19:48:38

US3042288

Folder: SAE USA-US052-2020-MRNA-1273-P301000025

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:40:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:10:56
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:49:34