

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

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:46:52

All time stamps listed in this document are displayed in GMT

US3242288

Form: Participant Creation

Generated On: 26 Nov 2020 10:46:52

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:46:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:46:52

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

Condition	HYPERPLASIA BILATERAL BREAST
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:11 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:11
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	209 lb
BMI (<i>xxx.x</i>)	32.80247 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

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2016
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes <input checked="" type="radio"/>	No <input type="radio"/>
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Other	Yes <input type="radio"/>	No <input checked="" type="radio"/>

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 10:46:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

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

What was the participant's randomization number? 111110

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:22
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

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)	3 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:00
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	03 SEP 2020
What was the treatment time? (00:00-23:59)	10:29 (24 HR)
Treatment Date and Time (derived)	03 SEP 2020 10:29
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 10:46:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:17 (24 HR)
Collection date and time (derived)	3 SEP 2020 10:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

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: 26 Nov 2020 10:46:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 11:02

PC Open Date & Time

03 SEP 2020 10:49

PC Close Date & Time

03 SEP 2020 13:19

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 11:02

PC Open Date & Time

03 SEP 2020 10:49

PC Close Date & Time

03 SEP 2020 13:19

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:40

PC Open Date & Time

03 SEP 2020 14:14

PC Close Date & Time

04 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 16:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

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

No ☒

Yes ☐

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

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

No ☒

Yes ☐

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

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 ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

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 ☒

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted?

Yes ☒

No ☐

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

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3242288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3242288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3242288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

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

Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3242288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted?

Yes ☒

No ☐

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

18 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted?

Yes ☒

No ☐

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

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted?

Yes ☒

No ☐

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

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	VISIT3

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	5 NOV 2020
Collection time (<i>00:00-23:59</i>)	16:28 (24 HR)
Collection date and time (derived)	5 NOV 2020 16:28

US3242288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 16:05:51

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

11 NOV 2020 10:29:11

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 11:35:06

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
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Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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"/>

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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 ☐

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3242288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

Symptom Day

Day 1	<input checked="" 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 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"/>
Day 33	<input type="checkbox"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 SEP 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	305 of 2072	

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature	100.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	309 of 2072	

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	313 of 2072	

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	317 of 2072	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	321 of 2072	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

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

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	325 of 2072	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" 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 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	329 of 2072	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 (8)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	333 of 2072	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" 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 checked="" type="checkbox"/>
Vomiting	None	<input checked="" 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 checked="" type="checkbox"/>
Sore Throat	None	<input checked="" 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 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	337 of 2072	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" 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 (10)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	341 of 2072	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" 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 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	345 of 2072	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	349 of 2072	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

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

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

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

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

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

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" 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 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

If Yes to either Did subject require any of the following:

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

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 _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:46:52

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:20
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	209 lb
Temperature (<i>xxx.x</i>)	99.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3242288

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:46:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 SEP 2020

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3242288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:46:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 OCT 2020

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Folder: Unscheduled 11 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:52

Visit Date

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

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Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Unscheduled 11 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:46:52

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)

Generated On: 26 Nov 2020 10:46:52

AEID	USA-US067-2020-MRNA-1273-P30 1000004
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

AEID

Adverse event

WORSENING HYPERLIPIDEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:46:52

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

Yes ☒

No ☐

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

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	CLONIDINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	0.1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (<i>dd MMM yyyy</i>)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	SIMVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	ARIMIDEX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERPLASIA IN BREAST TISSUE, BILATERAL
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FEVER(COVID-19 SYMPTOMS)
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	DAYQUIL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	FEVER AND CONGESTION (COVID-19 SYMPTOMS)
Dose per administration	325/10/5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS FOR INFLUENZA
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (<i>dd MMM yyyy</i>)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		12 OCT 2020
<hr/>		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	CRESTOR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	SHRINGRIX
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS FOR SHINGLES
Dose per administration	0.50
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

Name of Medication	RED YEAST RICE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SUPPLEMENT FOR HYPERLIPIDEMIA
Dose per administration	600
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

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

US3242288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:46:52

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:46:52

Date of dosing discontinuation (dd MMM yyyy)

14 SEP 2020

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 _____

US3242288

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:46:52

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3242288

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:46:52

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 11:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242288

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

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:46:52

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 13:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242288

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

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:46:52

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/SEP/2020 11:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242288

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

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:46:52

SAEID	USA-US067-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DRIVE ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/SEP/2020 12:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

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

US3242288

Form: Participant Creation

Generated On: 26 Nov 2020 10:46:52

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:29:23
User entered 'US3242288'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:35:10

US3242288

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:17

US3242288

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:30:53
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:35:11

US3242288

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:30:53
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:17

US3242288

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Sep 2020 13:58:17

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:35:12

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '58'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '58'	System	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered 'Female (F)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

White

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '1'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:52

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:45:13
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:31

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2020'	System	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:44

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:35:11

US3242288

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:17:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:46:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:07
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:37

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:24:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Sep 2020 14:24:49
Data point term sent to Coder	System	03 Sep 2020 14:24:16
User entered 'Hypertension'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2000'	System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:23:51

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:24:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:24:49
Data point term sent to Coder	System	03 Sep 2020 14:24:16
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2005'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2005'	System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:24:07

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:24:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:24:49
Data point term sent to Coder	System	03 Sep 2020 14:24:18
User entered 'Obesity'	Donna Toepfer (b) (4) (b) (4) (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2015'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2015'	System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:24:14

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:26:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:26:44
Data point term sent to Coder	System	03 Sep 2020 14:25:20
User entered 'Postmenopausal'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2016'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2016'	System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:24:22

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:26:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Sep 2020 14:26:44
Data point term sent to Coder	System	03 Sep 2020 14:25:18
User entered 'Bradycardia'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Un UNK 2010'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2010'	System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:25:01

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:27:49
Data point term sent to Coder	System	03 Sep 2020 14:26:21
User entered 'Gastric Sleeve'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2017'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN UNK 2017'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2017'	System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2017'	System	03 Sep 2020 14:25:25

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Breast hyperplasia, LLT: Bilateral mammary hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:38:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:38:43
Data point term sent to Coder	System	18 Sep 2020 16:31:18
User entered 'Hyperplasia bilateral breast'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'UN Aug 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:20
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered '2020'	System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:30:56

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 14:26:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 14:26:08
User entered '09:11' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Sep 2020 14:26:08
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 14:25:59
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 09:11'	System	03 Sep 2020 14:26:08
User entered empty.	System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered '67' in	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered '209' lb	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '32.80247'	System	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Sep 2020 14:25:59
DataPoint set to visible.	System	03 Sep 2020 13:58:51

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 14:25:59

US3242288

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:19

US3242288

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:56
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 17:01:35
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:18:31
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:19

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

[If No, what is the reason?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered 'UN UNK 2016'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:52

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:12
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:26:46

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered 'I'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:52

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:59:06
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:27:15

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:53:41
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Nov 2020 12:42:13
User entered '03 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:29
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:29
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Sep 2020 14:30:39

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:20:06

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered '111110'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:20:06

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:20:06

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:54

US3242288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:55:05
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Sep 2020 13:04:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:07:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:06:41

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '09:22'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 09:22'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '98.5' F	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '56'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '12'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '124'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '78'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:52

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '11:00'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 11:00'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '97.4' F	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '56'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '16'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '124'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:56:49
User entered '80'	Donna Toepfer (b) (4)	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 15:41:58

US3242288

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:25
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:59

US3242288

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:25
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:30:59

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:25:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:34:44
Query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	09 Nov 2020 14:34:33
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:34:26
User entered '03 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:34:26
User opened query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:05:19
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered '10:29'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 10:29'	System	09 Nov 2020 14:34:26
User entered '3 Sep 2020 10:29'	System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:32
User entered 'ONCE'	System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 14:31:54

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:42
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:42
User entered '10:17'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 10:17'	System	03 Sep 2020 14:32:13

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered '3 Sep 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:46:52

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:46:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:46:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered '10:15'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:46:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 10:15'	System	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:52

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:51
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 14:32:31

US3242288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:57:59
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:31:04

US3242288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:31:04

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:01:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	System	03 Sep 2020 15:02:08
User entered 'Yes (Y)'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:01:54', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	System	03 Sep 2020 15:02:08
User entered '97.4'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:01:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	System	03 Sep 2020 15:02:08
User entered 'No (N)'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:02', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ec75480-4770-4177-a8f9-a39d971b7570'	System	03 Sep 2020 15:02:08
User entered '03 Sep 2020 11:02'	System	03 Sep 2020 15:02:08

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 10:49'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:19'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:39:50', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	System	04 Sep 2020 01:40:09
User entered 'Yes (Y)'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:39:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	System	04 Sep 2020 01:40:09
User entered '98.4'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	System	04 Sep 2020 01:40:09
User entered 'No (N)'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'f64da26f-5712-4249-81f0-6e40c2e23d2c'	System	04 Sep 2020 01:40:09
User entered '03 Sep 2020 21:40'	System	04 Sep 2020 01:40:09

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:14'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 2'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:25', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	System	04 Sep 2020 16:21:42
User entered 'Yes (Y)'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	System	04 Sep 2020 16:21:42
User entered '98.2'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:34', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	System	04 Sep 2020 16:21:42
User entered 'No (N)'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '150ae904-8851-40b0-975f-5f01b7986792'	System	04 Sep 2020 16:21:42
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 16:21:42

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 3'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:07', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	System	05 Sep 2020 16:01:56
User entered 'Yes (Y)'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:12', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	System	05 Sep 2020 16:01:56
User entered '98.3'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:15', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	System	05 Sep 2020 16:01:56
User entered 'No (N)'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'dc931bc8-08a3-414d-b8b5-9061dc7a75ae'	System	05 Sep 2020 16:01:56
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:01:56

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 4'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:47', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	System	06 Sep 2020 20:55:05
User entered 'Yes (Y)'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:53', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	System	06 Sep 2020 20:55:05
User entered '98.3'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:56', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	System	06 Sep 2020 20:55:05
User entered 'No (N)'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:54:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '732fa334-4eef-44c2-b151-5d3c2a4fc0c2'	System	06 Sep 2020 20:55:05
User entered '06 Sep 2020 16:54'	System	06 Sep 2020 20:55:05

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 5'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	System	07 Sep 2020 16:05:19
User entered 'Yes (Y)'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	System	07 Sep 2020 16:05:19
User entered '98.6'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:12', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	System	07 Sep 2020 16:05:19
User entered 'No (N)'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:15', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0bfd7875-d9e1-4887-9ef3-95ce75b34115'	System	07 Sep 2020 16:05:19
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 16:05:19

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 6'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:22', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	System	08 Sep 2020 16:29:39
User entered 'Yes (Y)'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	System	08 Sep 2020 16:29:39
User entered '98.5'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:32', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	System	08 Sep 2020 16:29:39
User entered 'No (N)'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bf8b4818-1ffa-41ae-bf09-8d88891f4ac8'	System	08 Sep 2020 16:29:39
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 16:29:39

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 7'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	System	09 Sep 2020 16:15:20
User entered 'Yes (Y)'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	System	09 Sep 2020 16:15:20
User entered '97.9'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:13', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	System	09 Sep 2020 16:15:20
User entered 'No (N)'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:16', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '97e8528f-73c9-4f8f-8616-2098399b9ef6'	System	09 Sep 2020 16:15:20
User entered '09 Sep 2020 12:15'	System	09 Sep 2020 16:15:20

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	System	03 Sep 2020 15:02:25
User entered 'None (1)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:14', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	System	03 Sep 2020 15:02:25
User entered 'No (N)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:17', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	System	03 Sep 2020 15:02:25
User entered 'No (N)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:20', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	System	03 Sep 2020 15:02:25
User entered 'None (1)'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '36c282c7-6465-4038-b1ee-8a74fb997f0b'	System	03 Sep 2020 15:02:25
User entered '03 Sep 2020 11:02'	System	03 Sep 2020 15:02:25

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 10:49'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:19'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:09', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	System	04 Sep 2020 01:40:31
User entered 'None (1)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:18', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	System	04 Sep 2020 01:40:31
User entered 'No (N)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:21', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	System	04 Sep 2020 01:40:31
User entered 'No (N)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:24', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	System	04 Sep 2020 01:40:31
User entered 'None (1)'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:27', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2bf81aaa-e782-4b59-a110-13270b840dac'	System	04 Sep 2020 01:40:31
User entered '03 Sep 2020 21:40'	System	04 Sep 2020 01:40:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:14'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 2'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	System	04 Sep 2020 16:22:02
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	System	04 Sep 2020 16:22:02
User entered 'No (N)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:52', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	System	04 Sep 2020 16:22:02
User entered 'No (N)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:56', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	System	04 Sep 2020 16:22:02
User entered 'None (1)'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:21:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'c4d7c351-048a-4cf5-9da4-a1961d78006f'	System	04 Sep 2020 16:22:02
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 16:22:02

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 3'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:26', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	System	05 Sep 2020 16:02:35
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	System	05 Sep 2020 16:02:35
User entered 'No (N)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	System	05 Sep 2020 16:02:35
User entered 'No (N)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:36', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	System	05 Sep 2020 16:02:35
User entered 'None (1)'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:38', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '50c5430a-433a-42b5-9423-d13bc427a4f6'	System	05 Sep 2020 16:02:35
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:35

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 4'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	System	06 Sep 2020 20:55:16
User entered 'None (1)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:06', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	System	06 Sep 2020 20:55:16
User entered 'No (N)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	System	06 Sep 2020 20:55:16
User entered 'No (N)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:11', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	System	06 Sep 2020 20:55:16
User entered 'None (1)'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:13', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '6616c5a3-a743-4e21-9614-18407c489148'	System	06 Sep 2020 20:55:16
User entered '06 Sep 2020 16:55'	System	06 Sep 2020 20:55:16

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 5'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	System	07 Sep 2020 16:05:33
User entered 'None (1)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	System	07 Sep 2020 16:05:33
User entered 'No (N)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:26', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	System	07 Sep 2020 16:05:33
User entered 'No (N)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:28', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	System	07 Sep 2020 16:05:33
User entered 'None (1)'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:30', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'ed77dc3b-a36b-4ce0-97d2-127df0471d93'	System	07 Sep 2020 16:05:33
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 16:05:33

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 6'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	System	08 Sep 2020 16:29:54
User entered 'None (1)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:41', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	System	08 Sep 2020 16:29:54
User entered 'No (N)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:43', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	System	08 Sep 2020 16:29:54
User entered 'No (N)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:48', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	System	08 Sep 2020 16:29:54
User entered 'None (1)'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '4efef671-bd7f-4018-825f-a7be92e0c4d4'	System	08 Sep 2020 16:29:54
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 16:29:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 7'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	System	09 Sep 2020 16:15:31
User entered 'None (1)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:22', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	System	09 Sep 2020 16:15:31
User entered 'No (N)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:24', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	System	09 Sep 2020 16:15:31
User entered 'No (N)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:27', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	System	09 Sep 2020 16:15:31
User entered 'None (1)'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '7af70bde-7a06-4ae0-b16b-5af9b4608fc9'	System	09 Sep 2020 16:15:31
User entered '09 Sep 2020 12:15'	System	09 Sep 2020 16:15:31

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:28', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:30', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:33', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'None (0)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered 'No (N)'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T11:02:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '86021850-8428-4941-9a0b-d2dd3098cf2e'	System	03 Sep 2020 15:02:52
User entered '03 Sep 2020 11:02'	System	03 Sep 2020 15:02:52

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 10:49'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:19'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:33', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:41', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'None (0)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered 'No (N)'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-03T21:40:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '9c48bed8-f304-4b96-87f0-e0c494101613'	System	04 Sep 2020 01:40:56
User entered '03 Sep 2020 21:40'	System	04 Sep 2020 01:40:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:14'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 2'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:07', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:12', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'None (0)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:14', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered 'No (N)'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-04T12:22:17', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '2ea4e555-a81f-454e-b12f-073d14374f79'	System	04 Sep 2020 16:22:20
User entered '04 Sep 2020 12:22'	System	04 Sep 2020 16:22:20

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 3'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:44', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:48', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:50', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'None (0)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:54', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered 'No (N)'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-05T12:01:56', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '1b7b64de-049b-4243-be38-cd7e4cd34dcf'	System	05 Sep 2020 16:03:00
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:03:00

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 4'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:17', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:19', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:21', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:23', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:25', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:27', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'None (0)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:29', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered 'No (N)'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-06T16:55:31', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '595c4317-0395-4835-a67f-3e05c79d138a'	System	06 Sep 2020 20:55:35
User entered '06 Sep 2020 16:55'	System	06 Sep 2020 20:55:35

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 5'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:35', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:42', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:44', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:46', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'None (0)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:49', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered 'No (N)'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-07T12:05:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'b554b934-7726-4aa0-b05f-1f4ab370daff'	System	07 Sep 2020 16:05:56
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 16:05:56

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 6'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:55', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:57', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:29:59', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:01', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:04', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'None (0)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:08', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered 'No (N)'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-08T12:30:10', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '43ce90a5-525d-4e89-b1d6-c5c8f2bb3801'	System	08 Sep 2020 16:30:13
User entered '08 Sep 2020 12:30'	System	08 Sep 2020 16:30:13

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 7'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:32', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:34', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:36', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:37', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:39', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:41', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'None (0)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:43', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered 'No (N)'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-09-09T12:15:45', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: '0d0750e4-50f2-47e9-bd63-79acca1225c'	System	09 Sep 2020 16:15:50
User entered '09 Sep 2020 12:15'	System	09 Sep 2020 16:15:50

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:31:54

US3242288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:46:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	11 Sep 2020 13:35:18

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered '11 Sep 2020'	Grace Newville (b) (4) (b) (4)	11 Sep 2020 13:35:18

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	11 Sep 2020 13:35:18

US3242288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:42
User entered empty.	Grace Newville (b) (4) (b) (4)	11 Sep 2020 13:35:18

US3242288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:35:48
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	11 Sep 2020 13:36:05

US3242288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 13:36:05

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	21 Sep 2020 15:28:22

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered '18 Sep 2020'	Grace Newville (b) (4) (b) (4)	21 Sep 2020 15:28:22

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	21 Sep 2020 15:28:22

US3242288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:01
User entered empty.	Grace Newville (b) (4) (b) (4)	21 Sep 2020 15:28:22

US3242288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:09
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	21 Sep 2020 15:28:26

US3242288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 15:28:26

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:23
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:10:30

US3242288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:10:21

US3242288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 17:10:21

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:36
User closed query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 21:53:24
User opened query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 21:53:09
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:53:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:50:57
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Nov 2020 21:53:31
User entered empty; reason for change Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 21:53:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	05 Nov 2020 21:53:24
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	05 Nov 2020 21:53:24
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	05 Nov 2020 21:53:24
User entered ' Nov ' (non-conformant).	Erynn McKinley (b) (4)	05 Nov 2020 21:53:24
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	05 Nov 2020 21:50:57
User entered '5 Nov 2020' reason for change: Data Entry Error	System	05 Nov 2020 21:50:57
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 21:50:57
	(b) (4)	
	Donna Toepfer (b) (4)	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:36:36
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 21:53:09
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 21:50:57
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	27 Oct 2020 13:10:27

US3242288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:56:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:42:34

US3242288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 13:42:34

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:01
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:43:13

US3242288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:18

US3242288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 13:43:18

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:46
User entered empty.	Donna Toepfer (b) (4)	27 Oct 2020 13:43:56

US3242288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:37:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Oct 2020 13:44:01

US3242288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 13:44:01

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	29 Oct 2020 18:35:27

US3242288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:00
User entered empty.	Erynn McKinley (b) (4)	29 Oct 2020 18:35:27
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	29 Oct 2020 18:35:30
	(b) (4)	

US3242288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 18:35:30

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:12
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:53:50

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:12
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 21:53:50
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:12
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	05 Nov 2020 21:53:50
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 21:53:50

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '15:58'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Nov 2020 15:58'	System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '97.8' F	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '56'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '16'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '124'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:17
User entered '76'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:51
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 21:54:51

US3242288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:22
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 21:54:57
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:22
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 21:54:57
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:27
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:04

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:27
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:04
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:27
User entered '16:28'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:04
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Nov 2020 16:28'	System	05 Nov 2020 21:55:04

US3242288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:38:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 21:55:07
	(b) (4)	

US3242288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 21:55:07

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 64'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-05T16:05:40', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bcb522b6-d153-44eb-a4b7-afa452cea003'	System	05 Nov 2020 21:05:53
User entered 'No (N)'	System	05 Nov 2020 21:05:53

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-05T16:05:43', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bcb522b6-d153-44eb-a4b7-afa452cea003'	System	05 Nov 2020 21:05:53
User entered 'No (N)'	System	05 Nov 2020 21:05:53

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-05T16:05:51', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'bcb522b6-d153-44eb-a4b7-afa452cea003'	System	05 Nov 2020 21:05:53
User entered '05 Nov 2020 16:05:51'	System	05 Nov 2020 21:05:53

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 71'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-11T10:28:58', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd0b9fcc5-266f-4f8e-ab9c-656d3f2558eb'	System	11 Nov 2020 15:29:13
User entered 'No (N)'	System	11 Nov 2020 15:29:13

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-11T10:29:05', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd0b9fcc5-266f-4f8e-ab9c-656d3f2558eb'	System	11 Nov 2020 15:29:13
User entered 'No (N)'	System	11 Nov 2020 15:29:13

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-11T10:29:11', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'd0b9fcc5-266f-4f8e-ab9c-656d3f2558eb'	System	11 Nov 2020 15:29:13
User entered '11 Nov 2020 10:29:11'	System	11 Nov 2020 15:29:13

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered 'Day 78'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-17T11:35:00', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'eec088f6-ab2b-45aa-8709-16452ac1a103'	System	17 Nov 2020 16:35:10
User entered 'No (N)'	System	17 Nov 2020 16:35:10

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-17T11:35:03', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'eec088f6-ab2b-45aa-8709-16452ac1a103'	System	17 Nov 2020 16:35:10
User entered 'No (N)'	System	17 Nov 2020 16:35:10

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (724e798f86573f6e)', Time: '2020-11-17T11:35:06', User OID: 'PatientReportedOutcome (US3242288)', ODM File OID: 'eec088f6-ab2b-45aa-8709-16452ac1a103'	System	17 Nov 2020 16:35:10
User entered '17 Nov 2020 11:35:06'	System	17 Nov 2020 16:35:10

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 14:31:54

US3242288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 14:31:54
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 14:31:54

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Oct 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Nov 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Nov 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Nov 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Nov 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Nov 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:07:10

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:07:10

US3242288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:07:10
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:07:10

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:46:52

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:46:52

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 14:11:40
User entered '09:12' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Sep 2020 14:11:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 14:10:49
User entered '12:' (non-conformant).	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:46:52

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 09:12'	System	11 Sep 2020 14:11:40
User entered '11 Sep 2020 12:' (non-conformant).	System	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:46:52

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User entered 'Safety Call (Safety Call)'	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:46:52

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:31
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 14:10:49

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '9 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered '97'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:40:17
User entered '%'	System	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered '99.6' F	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:40:17
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:14:35

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM; Please reconcile the year.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:46:23
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 05:49:13
Query 'Per CDM; Please reconcile the year.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	11 Nov 2020 22:37:48
DataPoint Un-verified.	Donna Toepfer (b) (4)	11 Nov 2020 22:37:41
User entered '10 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Nov 2020 22:37:41
User opened query 'Per CDM; Please reconcile the year.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 21:47:26
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '10 Sep 2010' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered '12 Sep 2010'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered '97'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:42:39
User entered '%'	System	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '100.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered '99.8' F	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:42:39
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '11 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered '13 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.6' F	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:45:16
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	14 Sep 2020 19:16:55

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '12 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered '14 Sep 2020'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered '96'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.8' F	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:46:12
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:38:06

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '13 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered '16 Sep 2020'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered '98'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Sep 2020 22:39:13

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.6' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered '99.9' F	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:47:37
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	16 Sep 2020 22:39:13

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '14 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:48:27
User entered '16 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.8' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:48:27
User entered '99.1' F	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:48:27
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '15 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered '17 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered '97'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 13:02:56

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.9' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered '99.2' F	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 16:49:09
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 13:02:56

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '16 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.1' F	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Not Done (Not Done)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:50:17

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '17 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.2' F	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	18 Sep 2020 16:51:05

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '18 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.1' F	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:05:41

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '19 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.9' F	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:07:03

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '20 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '96'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '99.1' F	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	22 Sep 2020 13:08:24

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '21 Sep 2020'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.9' F	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	23 Sep 2020 12:26:51

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '22 Sep 2020'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.8' F	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:21:26

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:25:29
Query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08OCT2020. Please reconcile or clarify.' answered with 'symptoms ended' (Site from DM).	Donna Toepfer (b) (4)	09 Nov 2020 14:14:50
User opened query 'Per CDM: it appears there may be additional records of symptoms missing as there is a Convalescence Visit Day 28 recorded with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:08:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '23 Sep 2020'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '0'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '97'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered '98.7' F	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered 'None (None)'	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:46:52

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:42
User entered empty.	Donna Toepfer (b) (4)	24 Sep 2020 12:22:31

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:18:02
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirm, positive' (Site from System).	Donna Toepfer (b) (4)	14 Sep 2020 19:18:14
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	14 Sep 2020 19:18:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:07
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:46:52

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 19:18:01

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 14:06:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 14:06:24
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Sep 2020 14:06:24
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 14:03:34
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:46:52

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:41
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 14:03:34

US3242288

Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:46:52

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:58
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:33:17

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Re-query: Please confirm the Date of Collection for the Day 3 Saliva sample, since GCL has Day 3 recorded as 15SEP2020, and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:44:17
Query 'Per GCL Lab Reconciliation: Re-query: Please confirm the Date of Collection for the Day 3 Saliva sample, since GCL has Day 3 recorded as 15SEP2020, and update if appropriate.' answered with 'confirm date should be 13 Sep 2020' (Site from DM).	Donna Toepfer (b) (4)	03 Nov 2020 17:26:18
User opened query 'Per GCL Lab Reconciliation: Re-query: Please confirm the Date of Collection for the Day 3 Saliva sample, since GCL has Day 3 recorded as 15SEP2020, and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:37:11
User closed query 'Per GCL Lab Reconciliation: Saliva Sample day 3 reported under Illness visit is dated 15Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:37:11
Query 'Per GCL Lab Reconciliation: Saliva Sample day 3 reported under Illness visit is dated 15Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'symptom log does not match saliva log' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 19:34:03
User opened query 'Per GCL Lab Reconciliation: Saliva Sample day 3 reported under Illness visit is dated 15Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:16:30
User accepted default value 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '13 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '15 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva Sample reported under Illness visit is dated 21Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:19:58
Query 'Per GCL Lab Reconciliation: Saliva Sample reported under Illness visit is dated 21Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' answered with 'confirm date is 17 Sep 2020' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 19:35:10
User opened query 'Per GCL Lab Reconciliation: Saliva Sample reported under Illness visit is dated 21Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:17:31
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '17 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:44:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Date is correct 19Sep2020, no Saliva sample on 21Sep2020 per source' (Site from DM).	Donna Toepfer (b) (4)	06 Nov 2020 13:17:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:51:59
User accepted default value 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered '19 Sep 2020'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:19:09
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered with 'will update when completed' (Site from System).	Donna Toepfer (b) (4)	21 Sep 2020 18:29:40
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:29:00
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 25SEP2020 for Day 14 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Recon: Saliva: Samples dated 25SEP2020 for Day 14 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:18:53
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:09:37
	(b) (4), (b) (6)	29 Oct 2020 14:09:31
User entered '25 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:09:31
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 25SEP2020 for Day 14 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:33:46
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:10:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:19:15
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered with 'will update when subject completes' (Site from System).	Donna Toepfer (b) (4)	21 Sep 2020 18:29:51
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:29:00
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 02OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Recon: Saliva: Sample dated 02OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:19:24
DataPoint Un-verified.	Donna Toepfer (b) (4)	29 Oct 2020 14:09:52
	Donna Toepfer (b) (4)	29 Oct 2020 14:09:47
User entered '02 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	29 Oct 2020 14:09:47
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 02OCT2020 for Day 21 is reported under Illness visit in PPD central lab, however collection date is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:34:23
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:46:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:46:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:19:24
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered with 'will update when subject completes' (Site from System).	Donna Toepfer (b) (4)	21 Sep 2020 18:30:03
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 18:29:00
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
User entered '8 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Oct 2020 13:53:39
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:36:12
User entered empty.	Donna Toepfer (b) (4)	21 Sep 2020 18:29:00

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 15:36:44
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:51
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	21 Sep 2020 18:29:23
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 17:48:08
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 17:47:48
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 17:36:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:51
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:32:51
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '14:20'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:20'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '67' in	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19
DataPoint set to visible.	System	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '209' lb	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19
DataPoint set to visible.	System	14 Sep 2020 19:18:31

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '99.6' F	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '60'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 19:19:28
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	14 Sep 2020 19:19:28
User entered '14' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Sep 2020 19:19:28
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 19:19:19
User entered '174'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '128'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:13
User entered '70'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 19:19:19

US3242288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:25
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:41

US3242288

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:25
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:22:37
User entered '11 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Sep 2020 19:22:37
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:19:41
User entered '14 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:19:41

US3242288

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:46:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:39:03

US3242288

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:33:34
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:39:03

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:41
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:01
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Nov 2020 12:42:56
User entered '08 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:42:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:41
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:41
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '07:59'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020 07:59'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '67' in	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23
DataPoint set to visible.	System	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '209' lb	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23
DataPoint set to visible.	System	08 Oct 2020 13:51:40

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '97.3' F	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered empty.	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '60'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '16'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '128'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:47
User entered '82'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 13:52:23

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:55
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:35

US3242288

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:42:55
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:35

US3242288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:46:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:54

US3242288

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:46:52

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:01
User entered '8 Oct 2020'	Donna Toepfer (b) (4)	08 Oct 2020 13:52:54

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:52

[Visit Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:24:03
User closed query 'Per CDM; Please consider removing All data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:24:02
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:20
Query 'Per CDM; Please consider removing All data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	09 Nov 2020 14:26:02
Query 'Data is required. Please complete.' answered with 'deleted per DM, duplicate of Illness visit' (Site from System).	Donna Toepfer (b) (4)	09 Nov 2020 14:25:57
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:25:50
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:25:50
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:25:50
User opened query 'Per CDM; Please consider removing All data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit Day 1.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:07:25
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:13
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:04

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:52

[Physical Exam](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:20
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:25:50
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:25:50
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:13
User entered '1'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:04

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:52

[Vital Signs](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:20
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:25:50
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:25:50
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:13
User entered '1'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:04

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:52

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:13
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:04

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:52

[Pregnancy Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:13
User entered '0'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:04

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:23:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
Query 'Data is required. Please complete.' answered with 'deleted per DM, duplicate of Illness visit' (Site from System).	Donna Toepfer (b) (4)	09 Nov 2020 14:26:58
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:26:36
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:03
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:01
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '14:20'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:26:36
User entered '11 Sep 2020 14:20'	System	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '99.6' F	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:10
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered empty.	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:11
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '60'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:26:36
User entered 'bpm'	System	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:13
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '14'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:26:36
User entered 'breaths/min'	System	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '128'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:26:36
User entered 'mmHg'	System	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:19
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:36
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:23
User entered '70'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:26:36
User entered 'mmHg'	System	22 Sep 2020 22:28:30

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:23:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:24
Query 'Data is required. Please complete.' answered with 'deleted per DM, duplicate of Illness visit' (Site from System).	Donna Toepfer (b) (4)	09 Nov 2020 14:26:52
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:26:47
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:47
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:47
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:37
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:36

US3242288

Folder: Unscheduled 11 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:24
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Nov 2020 14:26:47
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	09 Nov 2020 14:26:47
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:34:37
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	22 Sep 2020 22:28:36

US3242288

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:46:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Sep 2020 19:06:59
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:21

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:27
User entered 'USA-US067-2020-mRNA-1273-P301000004'	System	15 Sep 2020 15:31:19
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 15:31:19

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: per sponsor review, Please consider updating term to Covid-19 ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:45:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:39:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:39:53
Data point term sent to Coder	System	17 Nov 2020 02:38:42
Query 'Per CDM: per sponsor review, Please consider updating term to Covid-19 ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	17 Nov 2020 02:38:33
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 02:38:27
Coding entries removed.	Donna Toepfer (b) (4)	17 Nov 2020 02:38:27
User entered 'COVID-19' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 02:38:27
User opened query 'Per CDM: per sponsor review, Please consider updating term to Covid-19 ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 14:15:53
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 19:12:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 19:12:52
Data point term sent to Coder	System	14 Sep 2020 19:12:08
User entered 'SARS COVID-19'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: The event start date is reported as 09-SEP-2020 however, there were no signs or symptoms reported on this date and date of positive test was 11-SEP-2020. Please provide signs and symptoms for this date, clarify that the covid-19 swab was taken on 09-SEP-2020, or update start date to the date of positive test. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:37:15
Query 'PV Query: The event start date is reported as 09-SEP-2020 however, there were no signs or symptoms reported on this date and date of positive test was 11-SEP-2020. Please provide signs and symptoms for this date, clarify that the covid-19 swab was taken on 09-SEP-2020, or update start date to the date of positive test. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 17:02:44
User opened query 'PV Query: The event start date is reported as 09-SEP-2020 however, there were no signs or symptoms reported on this date and date of positive test was 11-SEP-2020. Please provide signs and symptoms for this date, clarify that the covid-19 swab was taken on 09-SEP-2020, or update start date to the date of positive test. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:26:28
User entered '09 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 12:23:43
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:48:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	24 Sep 2020 12:23:53
User entered '23 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 12:23:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:24:26
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:18:48
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:11:17
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 18:27:51
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'confirm, AE of SARS COVID 19' (Site from System).	Donna Toepfer (b) (4)	14 Sep 2020 19:12:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:11:17
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:21:37
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	05 Oct 2020 15:22:55
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 22:42:15
User entered 'I'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

US3242288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:48:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	24 Sep 2020 12:24:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 12:23:43
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:25:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User closed query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19? ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:37:38
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:37:36
Query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19? ' answered with 'no known exposure' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 17:03:15
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 17:03:07
User opened query 'PV Query: Did the subject have any known exposure or risk factors for COVID-19? ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:25:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 16:24:44
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 19:11:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:39:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:39:20
Data point term sent to Coder	System	22 Oct 2020 17:50:11
User entered 'Worsening Hyperlipidemia'	Erynn McKinley (b) (4) (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '29 Sep 2020'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'No (N)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4) (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'None (NONE)'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '1'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered '0'	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4) (b) (4)	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:28
User entered empty.	Erynn McKinley (b) (4)	22 Oct 2020 17:50:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 17:50:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:46:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 17:50:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:46:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:38
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:27:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:29:47
Data point term sent to Coder	System	03 Sep 2020 14:29:28
User entered 'Clonidine'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Hypertension'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0.1'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:28:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:30:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:30:47
Data point term sent to Coder	System	03 Sep 2020 14:29:32
User entered 'Simvastatin'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '20'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Un UNK 2005'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:29:12

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE, PRODUCTSYNONYM: ARIMIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:57:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:57:34
Data point term sent to Coder	System	19 Oct 2020 15:56:32
Coding entries removed.	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE, PRODUCTSYNONYM: ARIMIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:31:41
Data point term sent to Coder	System	03 Sep 2020 14:30:33
User entered 'Arimidex'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:22:51
Query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 15:56:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
User opened query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:14:47
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
User entered 'HYPERPLASIA IN BREAST TISSUE, Bilateral' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 15:55:53
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Prevent hyperplasia in breast tissue'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '1'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Un Aug 2020'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 14:29:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
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)	05 Oct 2020 15:24:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:24:22
Data point term sent to Coder	System	05 Oct 2020 15:23:12
Coding entries removed.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:02
Data point term sent to Coder	System	18 Sep 2020 16:33:24
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:13
User entered 'FEVER(COVID-19 symptoms)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Oct 2020 15:22:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Fever'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '500'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'mg (mg)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:04:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '23 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:04:52
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:23:29
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 15:56:30
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 15:56:23
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 15:56:23
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:50:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:32:40

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:24:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:24:23
Data point term sent to Coder	System	05 Oct 2020 15:23:12
Coding entries removed.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:35
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:02
Data point term sent to Coder	System	18 Sep 2020 16:33:26
User entered 'Dayquil'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	05 Oct 2020 15:22:35
User entered 'FEVER and congestion (COVID-19 symptoms)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Oct 2020 15:22:35
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Fever'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:24:56
Query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify. ' answered with 'med is a tablet' (Site from DM). User opened query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify. ' (Site from DM). User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Donna Toepfer (b) (4)	09 Nov 2020 17:45:46 09 Nov 2020 14:11:27
User opened query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Please review and update as appropriate. Otherwise, clarify. ' (Site from DM). User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 14:08:34
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 20:22:35
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 18:24:08
User entered '325/10/5' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dosefor this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 05:15:34
	(b) (4), (b) (6) (b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '2'	Donna Toepfer (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59
User entered 'mg (mg)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 18:23:59
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'capsule (CAPSULE)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '0'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:05:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered '24 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Sep 2020 13:05:12
User entered empty.	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:23:53
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 18:24:32
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Oct 2020 18:24:27
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 18:24:27
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and AE eCRF within this timeframe. Review response if this should be updated to "No" as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:33:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:30:53
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:33:15

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:49:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	05 Nov 2020 22:49:24
Data point term sent to Coder	System	05 Nov 2020 22:48:40
User entered 'Influenza Vaccine'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Prophylaxis for Influenza'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0.5'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mL (mL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '12 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '12 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:48:35

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:50:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:50:31
Data point term sent to Coder	System	05 Nov 2020 22:49:42
User entered 'Crestor'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Hyperlipidemia'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '20'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mg (mg)'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '29 Sep 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:49:37
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 22:49:37

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:54
Data point term sent to Coder	System	05 Nov 2020 22:51:43
User entered 'Shringrix'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Prophylaxis for shingles'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0.50'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mL (mL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:50:43
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:50:43

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED YEAST RICE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:48:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:48:29
Data point term sent to Coder	System	05 Nov 2020 22:51:43
User entered 'Red Yeast Rice'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Supplement for Hyperlipidemia'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '600'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'mg (mg)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'twice daily (BID)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	05 Nov 2020 22:52:08
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Nov 2020 22:52:08
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Nov 2020 22:51:32
User entered '26 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:46
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:51:32
	(b) (4)	

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 22:51:32

US3242288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:46:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:31:06
User entered 'No (N)'	Donna Toepfer (b) (4)	03 Sep 2020 14:30:11

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:46:52

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:06
User entered '14 Sep 2020'	Donna Toepfer (b) (4)	14 Sep 2020 19:06:46

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:46:52

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:06
User entered 'Due to SARS-COV-2 (COVID)'	Donna Toepfer (b) (4)	14 Sep 2020 19:06:46

US3242288

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:47:06
User entered empty.	Donna Toepfer (b) (4)	14 Sep 2020 19:06:46

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:46:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '15/Sep/2020 11:31'	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:46:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:46:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '15/Sep/2020 13:24'	System	15 Sep 2020 17:24:04

US3242288

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

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:46:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:37:48
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 17:24:04

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:46:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '22/Sep/2020 11:37'	System	22 Sep 2020 15:38:02

US3242288

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

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:46:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 15:38:02

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'USA-US067-2020-MRNA-1273-P301000004'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'No (N)'	System	15 Sep 2020 15:31:19

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Nathan' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Nathan'	System	15 Sep 2020 15:31:19

US3242288

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Segall' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Segall'	System	15 Sep 2020 15:31:19

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '175 Country Club Drive St100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '175 country club dr st100a'	System	15 Sep 2020 15:31:19

US3242288

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered 'Stockbridge'	System	15 Sep 2020 15:31:19

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Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '175 Country Club Drive St 100a Stockbridge Ga 3028'	Donna Toepfer (b) (4)	29 Sep 2020 13:13:25

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Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:04
Un-reviewed for Safety.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
User entered '30281' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Sep 2020 17:30:08
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 16:48:50
Un-reviewed for Safety.	System	22 Sep 2020 15:38:02
User entered empty.	System	22 Sep 2020 15:38:02
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:31:47
User entered '30281'	System	15 Sep 2020 15:31:19

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 05:07:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:23:42
User entered 'US' (non-conformant).	System	15 Sep 2020 15:31:56

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 16:49:03
User entered '3'	System	22 Sep 2020 15:38:02
User entered '2'	System	15 Sep 2020 17:24:04
User entered '1'	System	15 Sep 2020 15:31:56

US3242288

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

Form: Safety Report Form (4)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered '24/Sep/2020 12:49'	System	24 Sep 2020 16:49:03

US3242288

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

Form: Safety Report Form (4)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:06
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 16:49:03