

US3472096 (Prod: Penn Prevention - (CRS))

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:29:46

All time stamps listed in this document are displayed in GMT

US3472096

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:46

[Participant ID](#)

US3472096

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	True
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 09:29:46

Date of Informed Consent (<i>dd MMM yyyy</i>)	7 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:46

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

Condition	BORDERLINE PERSONALITY DISORDER
Start date (dd MMM yyyy)	UN JAN 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 09:29:46

Condition	HERNIATED DISC, L5-S1
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	SEP 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

Condition	CHOLYCYSTECTOMY
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

Condition	SEBORRHEIC DERMITITIS, PERIORAL
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 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 09:29:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:27 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:27
Height (<i>xxx.x</i>)	190.5 cm
Weight (<i>xxx.x</i>)	126 kg
BMI (<i>xxx.x</i>)	34.72007 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 09:29:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify IT

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 09:29:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

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

What was the participant's randomization number? 116343

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 09:29:46

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 09:29:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:27
Temperature (xxx.x)	37.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 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 09:29:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:23
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

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 09:29:46

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	7 OCT 2020
What was the treatment time? (00:00-23:59)	13:01 (24 HR)
Treatment Date and Time (derived)	7 OCT 2020 13:01
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 OCT 2020

Collection time (00:00-23:59)

11:55 (24 HR)

Collection date and time (derived)

7 OCT 2020 11:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:46

Collection date (dd MMM yyyy)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:47	7 OCT 2020 11:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

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 09:29:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 13:26

PC Open Date & Time

07 OCT 2020 13:21

PC Close Date & Time

07 OCT 2020 15:51

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 07 OCT 2020 18:03

PC Open Date & Time 07 OCT 2020 16:46

PC Close Date & Time 08 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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 OCT 2020 12:35

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

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

98.2 °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

09 OCT 2020 16:29

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

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

10 OCT 2020 20:43

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

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

98.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 OCT 2020 19:06

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.3 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	12 OCT 2020 12:45
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	13 OCT 2020 20:48
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 8

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 97.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 14 OCT 2020 12:37

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 9

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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	15 OCT 2020 20:06
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 10

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

16 OCT 2020 14:29

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 13:26

PC Open Date & Time

07 OCT 2020 13:21

PC Close Date & Time

07 OCT 2020 15:51

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 17:52

PC Open Date & Time

07 OCT 2020 16:46

PC Close Date & Time

08 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

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

08 OCT 2020 12:36

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

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

09 OCT 2020 12:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

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

10 OCT 2020 20:42

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

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

11 OCT 2020 19:05

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

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

12 OCT 2020 12:46

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

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

13 OCT 2020 20:48

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 13:27
PC Open Date & Time	07 OCT 2020 13:21
PC Close Date & Time	07 OCT 2020 15:51

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 17:53
PC Open Date & Time	07 OCT 2020 16:46
PC Close Date & Time	08 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

Yes ☐	
PC Time stamp	08 OCT 2020 12:36
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

Yes ☐	
PC Time stamp	09 OCT 2020 12:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

Yes ☐	
PC Time stamp	10 OCT 2020 20:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

Yes ☐	
PC Time stamp	11 OCT 2020 17:47
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

Yes ☐	
PC Time stamp	12 OCT 2020 12:46
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

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 ☒

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

Yes ☐	
PC Time stamp	13 OCT 2020 20:49
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 OCT 2020 12:37
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 OCT 2020 20:06
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 OCT 2020 14:28
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 11:02
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

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

PARTICIPANT NEEDED TO
LEAVE FOR ANOTHER
APPOINTMENT.

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? _____

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	04 NOV 2020
Collection time (<i>00:00-23:59</i>)	11:09 (24 HR)
Collection date and time (derived)	04 NOV 2020 11:09

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:46

Collection date (dd MMM yyyy)			04 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	04 NOV 2020 11:06
Nasopharyngeal Swab 2	No		

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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05 FEB 2021 00:01

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09 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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12 FEB 2021 00:01

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16 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 138

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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19 FEB 2021 00:01

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23 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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02 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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09 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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16 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 166

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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23 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 173

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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20 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 208

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 222

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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22 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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12 NOV 2021 00:01

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16 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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23 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

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07 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

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28 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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01 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

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 ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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08 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

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15 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

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22 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

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](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

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 ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

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 ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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06 MAY 2022 00:01

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10 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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20 MAY 2022 00:01

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24 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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31 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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07 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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14 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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02 SEP 2022 00:01

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06 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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13 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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20 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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27 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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30 SEP 2022 00:01

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04 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

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11 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

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08 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2022 23:59

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:46

Date of Contact	09 NOV 2020
Time of Contact	09:45
Date and Time of Contact (derived)	09 NOV 2020 09:45
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	295 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	299 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	303 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	307 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	311 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	315 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	319 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	323 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	327 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	331 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	335 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	339 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	343 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	347 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	351 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☒
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	355 of 2015	

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

Date of Visit	10 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	10 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

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 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

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 _____

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:29:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	16 NOV 2020
Day 9	Yes	18 NOV 2020
Day 14	Yes	23 NOV 2020
Day 21	No	
Day 28	No	

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	10 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	13:15 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 13:15
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	99.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
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)	

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3472096

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:29:46

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 NOV 2020

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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 _____

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Were vital signs assessed?	Yes ☐
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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)	

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

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.

US3472096

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:29:46

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

AEID	USA-US122-2020-MRNA-1273-P30 1000003
Adverse event	COVID-19
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)	09 NOV 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	
v6.020 DTW (1102)	373 of 2015

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:46

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

Yes ☒

No ☐

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

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	AS NEEDED PAIN RELIEF
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	TEGRETOL
Prophylaxis	Yes ☐ No ☒
Indication	BPD
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	ZOLOFT
Prophylaxis	Yes ☐ No ☒
Indication	BPD
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	DYMISTA NASAL SPRAY
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	SPRAYS
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

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

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	ALLERGY SHOTS
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☒ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☒
	803	☐
	804	☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	KETOCONAZOLE CREAM
Prophylaxis	Yes ☐ No ☒
Indication	SEBORRHEIC DERMITITIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	INFLUENZA VACCINATION
Prophylaxis	Yes ☒
	No ☐

Indication	INFLUENZA PROPHYLAXIS

Dose per administration	0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 21 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	5000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	VITAMIN C
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	ZINC LOZENGES
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	UNK
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	180
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3472096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:46

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:46

Date of dosing discontinuation (dd MMM yyyy)

09 NOV 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

US3472096

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:29:46

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 ☐

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

SAEID	USA-US122-2020-MRNA-1273-P301000003
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:46

SAEID	USA-US122-2020-MRNA-1273-P301000003
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	16/NOV/2020 14:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3472096 (Prod: Penn Prevention - (CRS))

US3472096

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:46

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3472096'	RWS_ENDPOINT ENDPOINT (b) (4) 	07 Oct 2020 15:22:51

US3472096

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:53

US3472096

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:54

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '42'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '42'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'Male (M)'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '1'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '1'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:46

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:35:22
	(b) (4)	

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 17:32:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 17:32:54
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Jie Ho (b) (4)	07 Oct 2020 17:32:54
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 17:12:35
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:53

US3472096

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:50
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:42:40

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Psychiatric disorders, HLGT: Personality disorders and disturbances in behaviour, HLT: Personality disorders with dramatic behaviour (Cluster B), PT: Borderline personality disorder, LLT: Borderline personality disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:48:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:48:56
Data point term sent to Coder	System	07 Oct 2020 18:43:54
User entered 'Borderline personality disorder'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Jan 2000'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:43:21
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2000'	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 13:30:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 13:30:40
Data point term sent to Coder	System	07 Oct 2020 18:45:05
User entered 'Herniated disc, L5-S1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2005'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Sep 2005'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:44:26
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Sep 2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 18:51:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Oct 2020 18:51:16
Data point term sent to Coder	System	07 Oct 2020 18:45:06
User entered 'Cholecystectomy'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Oct 2019'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 04:38:06
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	27 Oct 2020 02:53:14
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	27 Oct 2020 02:52:40
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:31:31
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Oct 2019' reason for change: Data Entry Error	Jie Ho (b) (4)	27 Oct 2020 02:52:40
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:04
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Oct 2019'	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2019'	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Oct 2019'	System	27 Oct 2020 02:52:40
User entered empty.	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2019'	System	27 Oct 2020 02:52:40
User entered empty.	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:54:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:54:09
Data point term sent to Coder	System	07 Oct 2020 18:46:09
User entered 'Seasonal allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 1996'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:45:33
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Jan 1996'	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '1996'	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Seborrhoeic dermatitis, LLT: Seborrheic dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:59:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:59:23
Data point term sent to Coder	System	07 Oct 2020 18:47:13
User entered 'Seborrheic dermititis, perioral'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2017'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:17
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2017'	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
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)	07 Oct 2020 18:56:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:56:15
Data point term sent to Coder	System	07 Oct 2020 18:47:13
User entered 'obesity'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:46:34
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:46:34
	(b) (4)	

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '11:27'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020 11:27'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '190.5' cm	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '126' kg	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '34.72007'	System	07 Oct 2020 18:37:15
DataPoint set to visible.	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	07 Oct 2020 18:37:15
DataPoint set to visible.	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
	(b) (4)	

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:29
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:47

US3472096

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:29
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:37:47
	(b) (4)	

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[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)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

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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)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

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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)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered 'IT'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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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)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '1'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:46

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:38:38
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:39:17
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:39:17
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered 'Clinic (Clinic)'	Petra Alexander (b) (4)	07 Oct 2020 18:39:17
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	07 Oct 2020 18:39:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered '116343'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:32:54

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:46

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:46

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:46

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:46

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '11:27'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020 11:27'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '37.3' C	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Oral (Oral)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '75'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '16'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '165'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '93'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:46

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:46

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '13:23'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020 13:23'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '37.1' C	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Oral (Oral)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '69'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '16'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '155'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 18:40:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '88'	Petra Alexander (b) (4)	07 Oct 2020 18:40:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:21
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:01
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:21
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:41:01
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:37:27
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered '13:01'	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020 13:01'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered 'ONCE'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:41:14
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered '11:55'	Petra Alexander (b) (4)	07 Oct 2020 18:41:14
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020 11:55'	System	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered '7 Oct 2020'	Petra Alexander (b) (4)	07 Oct 2020 18:41:33
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:33
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered '11:47'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020 11:47'	System	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:33
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:46
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 18:41:43
	(b) (4)	

US3472096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:41:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:25:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered 'Yes (Y)'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:25:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered '98.8'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered 'No (N)'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered '07 Oct 2020 13:26'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:02:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered 'Yes (Y)'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered '98.5'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:05', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered 'No (N)'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:08', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered '07 Oct 2020 18:03'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:34:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered 'Yes (Y)'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered '97.5'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered 'No (N)'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:28:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered '98.2'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered 'No (N)'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered '09 Oct 2020 16:29'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered 'Yes (Y)'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered '98.3'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered 'No (N)'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered '10 Oct 2020 20:43'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '98.3'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:54:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '1'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '0'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '11 Oct 2020 19:06'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered 'Yes (Y)'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '97.3'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered 'Yes (Y)'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '1'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '0'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '12 Oct 2020 12:45'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered 'Yes (Y)'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '98.2'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered 'Yes (Y)'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '1'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '0'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '13 Oct 2020 20:48'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 16:45:50
User entered 'Day 8'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered 'Yes (Y)'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '97.3'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered 'Yes (Y)'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '1'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '0'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:48:37
User entered 'Day 9'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '98.2'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '1'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211' User entered '0'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 16:37:57
User entered 'Day 10'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f'	System	16 Oct 2020 18:29:08
User entered 'Yes (Y)'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f' User entered '98.4'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:29:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f'	System	16 Oct 2020 18:29:08
User entered 'No (N)'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:29:03', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f' User entered '16 Oct 2020 14:29'	System	16 Oct 2020 18:29:08
	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-07T13:26:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'No (N)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'No (N)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-07T13:26:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'None (1)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered '07 Oct 2020 13:26'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-07T17:52:18', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'None (1)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'No (N)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'No (N)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-07T17:52:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'None (1)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered '07 Oct 2020 17:52'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-08T12:35:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'None (1)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'No (N)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'No (N)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-08T12:36:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'None (1)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered '08 Oct 2020 12:36'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-09T12:02:58', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'None (1)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'No (N)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'No (N)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-09T12:03:15', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'None (1)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:17', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered '09 Oct 2020 12:03'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-10T20:42:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'None (1)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'No (N)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'No (N)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-10T20:42:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'None (1)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered '10 Oct 2020 20:42'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-11T19:05:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'None (1)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'No (N)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'No (N)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-11T19:05:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'None (1)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered '11 Oct 2020 19:05'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-12T12:45:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'None (1)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'No (N)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'No (N)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-12T12:45:58', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'None (1)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered '12 Oct 2020 12:46'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-13T20:48:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'None (1)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'No (N)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'No (N)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-13T20:48:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'None (1)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered '13 Oct 2020 20:48'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:16', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-07T13:27:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'No (N)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered '07 Oct 2020 13:27'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:03', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:05', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-07T17:53:10', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'No (N)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered '07 Oct 2020 17:53'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-08T12:36:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'No (N)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered '08 Oct 2020 12:36'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:20', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'Some interference with activity (2)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-09T12:02:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'No (N)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'Some interference with activity (2)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-10T20:42:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'No (N)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:37', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered '10 Oct 2020 20:42'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:17', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:20', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:22', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-11T17:47:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'No (N)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered '11 Oct 2020 17:47'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:07', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:09', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:13', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-12T12:46:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'No (N)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered '12 Oct 2020 12:46'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:55', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-13T20:49:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'No (N)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:49:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered '13 Oct 2020 20:49'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 16:45:50
User entered 'Day 8'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-14T12:37:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '48f30f7b-4f8d-4c5e-8a4f-d3d04c5543ce'	System	14 Oct 2020 16:37:37
User entered 'No (N)'	System	14 Oct 2020 16:37:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '48f30f7b-4f8d-4c5e-8a4f-d3d04c5543ce' User entered '14 Oct 2020 12:37'	System	14 Oct 2020 16:37:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:48:37
User entered 'Day 9'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-15T20:06:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'afeffa1e-60d2-4ae9-b38c-eb3702e25261'	System	16 Oct 2020 00:06:56
User entered 'No (N)'	System	16 Oct 2020 00:06:56

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'afeffa1e-60d2-4ae9-b38c-eb3702e25261'	System	16 Oct 2020 00:06:56
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 00:06:56

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 16:37:57
User entered 'Day 10'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:46

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 (12282b35a699ff53)', Time: '2020-10-16T14:28:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '275b81b5-ff55-4d47-8517-b1cd758f5387'	System	16 Oct 2020 18:28:51
User entered 'No (N)'	System	16 Oct 2020 18:28:51

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '275b81b5-ff55-4d47-8517-b1cd758f5387'	System	16 Oct 2020 18:28:51
User entered '16 Oct 2020 14:28'	System	16 Oct 2020 18:28:51

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:37:57

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:38:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:47:54

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 22:47:54

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:00:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 17:56:35

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:56:35

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:00:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:51:52

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:51:52

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:02'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:02'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '17'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '170'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '91'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:26:15

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 16:26:15

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered 'Participant needed to leave for another appointment.'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:09'	(b) (4), (b) (6)	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:09'	System	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:06'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:06'	System	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:26:50

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 16:26:50

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

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 11:57:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

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 11:57:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:57:14

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

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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 11:57:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:57:14

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:46

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:54
User closed query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:13:33
Query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' answered with 'Thanks for your guidance. I personally did not receive a slide deck on 04SEP2020 but I will check with our CRA to see what this refers to. Severity Assessment completed.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:38:40
User opened query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:34:37
User closed query 'Please reconcile and add severity page as required.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:34:37
Query 'Please reconcile and add severity page as required.' answered with 'We are in communication with our CRA to determine exactly when the severity assessment needs to be completed as it is unclear to us after review of the protocol and CCGs.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:20:52
User opened query 'Please reconcile and add severity page as required.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:42:07
User entered '09 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:46

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered '09:45'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 09:45'	System	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:46

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User closed query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:12:43
Query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' answered with 'Updated the Symptom log to accurately reflect Symptom Day.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:55:39
User opened query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:35:33
User closed query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:35:33
Query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' answered with 'Per protocol, Day 1 is the Illness Visit.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 02:54:52
User opened query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:42:30
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.1' F	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:11
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.1' F	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '12 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '94'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '100.0' F	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.1' F	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '14 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '100.0' F	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User closed query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 23:32:49
	(b) (4), (b) (6)	19 Nov 2020 15:48:49
Query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	17 Nov 2020 03:17:13
User opened query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:12:33
User entered '15 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.0' F	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 1 (Day 1)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '09 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99' F	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '16 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '95'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Nov 2020 17:16:46

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.0' F	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '17 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.4' F	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.9' F	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change:	(b) (4), (b) (6)	22 Nov 2020 22:10:18
Data Entry Error		
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.5' F	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Date](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:29:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 14:51:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 14:51:04
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE added to Log.' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:25:58
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	12 Nov 2020 22:35:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:35:22
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:16:56
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:39:33
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:39:23
User entered 'No (N)' reason for change: Data Entry Jie Ho Error	(b) (4)	12 Nov 2020 22:39:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:39:23
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:17:10
User entered 'PENDING' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:17:10
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:17:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:17:10
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:35:22

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '93' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:31:40
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:31:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:31:40
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:31:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:29:46

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '12 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:38:05
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:38:05
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '18 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:21
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:38
User closed query 'Please reconcile and add saliva page' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:33:39
Query 'Please reconcile and add saliva page' answered with 'Saliva log updated.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:14:27
User opened query 'Please reconcile and add saliva page' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:41:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:38
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:38
User entered 'Home (Home)'	(b) (4), (b) (6)	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '13:15'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 13:15'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11
DataPoint set to visible.	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11
DataPoint set to visible.	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '99.1' F	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '80'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '17'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:17

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:46

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:56
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:18:17

US3472096

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:29:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:24

US3472096

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:03
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:18:24

US3472096

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:29:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 13:14:59
Query 'Data is required. Please complete.' answered with 'erroneously entered to D28' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:18:27
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:18:11
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:18:11
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:17:49

US3472096

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:29:46

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:18:11
User entered '10 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:17:49

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:36
User closed query 'Please reconcile and add COVID 19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:37:06
Query 'Please reconcile and add COVID 19 as central lab provided positive illness results' answered with 'Updated AE log.' (Site from CRA).	(b) (4)	16 Nov 2020 03:32:25
User opened query 'Please reconcile and add COVID 19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:41:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:46

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:53:58
User entered 'USA-US122-2020-mRNA-1273-P301000003'	System	16 Nov 2020 19:53:36
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 19:53:36

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
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)	16 Nov 2020 03:26:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:26:02
Data point term sent to Coder	System	16 Nov 2020 03:25:09
User entered 'COVID-19'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' answered with '09Nov2020 is on the symptom log..please clarify.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:21:34
User opened query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '09 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'This is marked ongoing..please clarify query.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:22:14
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:45:48
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'Updated.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:27:23
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Related (RELATED)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Not Related (NOT RELATED)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

Action taken with investigational product

Audit	User	Time (GMT)
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)	23 Nov 2020 15:33:15
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 'Reason was changed to "Due to SARSCOV2.' (Site from System).	Jie Ho (b) (4)	23 Nov 2020 04:29:46
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Updated.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:28:02
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	23 Nov 2020 04:27:41
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '1'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:28:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:28:34
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 03:24:37

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:48
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:49

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:39:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:39:24
Data point term sent to Coder	System	07 Oct 2020 18:49:18
User entered 'ibuprofen'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed pain relief'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '400'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4)	07 Oct 2020 18:49:11
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:49:11
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CARBAMAZEPINE, PRODUCTSYNONYM: TEGRETOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:45:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:45:59
Data point term sent to Coder	System	07 Oct 2020 18:50:20
User entered 'tegretol'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'BPD'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '400'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4)	07 Oct 2020 18:49:56
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 18:49:56
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:28:50
Data point term sent to Coder	System	07 Oct 2020 19:42:21
User entered 'zoloft'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'BPD'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '200'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '01 Sep 2020'	Petra Alexander (b) (4)	07 Oct 2020 19:42:19
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 19:42:19
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 14:54:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 14:54:20
Data point term sent to Coder	System	07 Oct 2020 19:43:25
User entered 'Dymista nasal spray'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '2'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'sprays'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:44
Data point term sent to Coder	System	07 Oct 2020 19:44:28
User entered 'Allergy shots'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Injection'	Petra Alexander (b) (4)	07 Oct 2020 19:44:05
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'every month (QM)'	Petra Alexander (b) (4)	07 Oct 2020 19:44:05
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 19:44:05
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2016'	Petra Alexander (b) (4)	07 Oct 2020 19:44:05
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 19:44:05
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:01:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:01:22
Data point term sent to Coder	System	07 Oct 2020 19:45:33
User entered 'ketoconazole cream'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Seborrheic dermatitis'	Petra Alexander (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Application'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Topical (TOPICAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2017'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4)	07 Oct 2020 19:45:04
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
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)	04 Nov 2020 16:54:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 16:54:25
Data point term sent to Coder	System	04 Nov 2020 16:38:57
Data point term sent to Coder	System	04 Nov 2020 16:28:42
User entered 'Influenza vaccination'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0.5'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mL (mL)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 16:38:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 16:38:24
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:38:24
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 16:27:48
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '21 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '21 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Vitamin D3'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '5000'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'IU (IU)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Vitamin C'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1000'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:55:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:55:39
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Zinc lozenges'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'UNK'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:03:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:03:36
Data point term sent to Coder	System	12 Nov 2020 23:03:09
User entered 'Azithromycin'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'COVID-19'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '500'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:12:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:12:41
Data point term sent to Coder	System	12 Nov 2020 23:04:10
User entered 'Albuterol'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'COVID-19'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '180'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User entered 'ug (ug)' reason for change: Data Entry Jie Ho	(b) (4)	23 Nov 2020 04:30:20
Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:33:35
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	23 Nov 2020 04:30:28
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:53:18
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mcg'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:41:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:41:20
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 19:41:20
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:41:07
User entered empty; reason for change Data Entry Error	Petra Alexander (b) (4)	07 Oct 2020 19:41:07
User entered 'Yes (Y)'	Petra Alexander (b) (4)	07 Oct 2020 19:40:42

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:46

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:46

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

Audit	User	Time (GMT)
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered '16/Nov/2020 14:54'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:46

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)	19 Nov 2020 15:39:43
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 19:54:17