

US3452295 (Prod: Lynn Health Science Institute)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:28:12

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US3452295

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:12

[Participant ID](#)

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

US3452295

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 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 09:28:12

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	63
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

Date of Informed Consent (<i>dd MMM yyyy</i>)	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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 09:28:12

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:12

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

Condition	LOW TESTOSTERONE
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 (4)

Generated On: 26 Nov 2020 09:28:12

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

Condition	SINUS SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

Condition	ALLERGY TO SACCHARIN
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

Condition	CHRONIC SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:32 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:32
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	254.8 lb
BMI (<i>xxx.x</i>)	35.61169 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 09:28:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 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 09:28:12

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101810

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

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 09:28:12

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)	06 AUG 2020
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:32
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 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 09:28:12

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)	06 AUG 2020
Time of assessment (00:00-23:59)	17:26 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 17:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 16:46 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 16:46

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 09:28:12

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

06 AUG 2020

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

16:40 (24 HR)

Collection date and time (derived)

06 AUG 2020 16:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:12

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:37	06 AUG 2020 16:37
Nasopharyngeal Swab 2	Yes	16:37	06 AUG 2020 16:37

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

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 09:28:12

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

98.2 °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

06 AUG 2020 17:22

PC Open Date & Time

06 AUG 2020 17:06

PC Close Date & Time

06 AUG 2020 19:36

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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 06 AUG 2020 20:31

PC Open Date & Time 06 AUG 2020 20:31

PC Close Date & Time 07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

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	99.9 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	07 AUG 2020 18:45
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

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	100.5 °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):

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

PC Time Stamp	09 AUG 2020 00:35
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

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

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 AUG 2020 21:58

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

10 AUG 2020 17:40

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

11 AUG 2020 23:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

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	98.0 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True
PC Time Stamp	13 AUG 2020 04:04
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

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

97.8 °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 13 AUG 2020 21:31

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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

06 AUG 2020 17:23

PC Open Date & Time

06 AUG 2020 17:06

PC Close Date & Time

06 AUG 2020 19:36

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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

06 AUG 2020 20:32

PC Open Date & Time

06 AUG 2020 20:31

PC Close Date & Time

07 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

30

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:48

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

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 AUG 2020 00:36

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

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

09 AUG 2020 21:58

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

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

10 AUG 2020 17:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

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

11 AUG 2020 23:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

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 AUG 2020 04:04

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 17:23
PC Open Date & Time	06 AUG 2020 17:06
PC Close Date & Time	06 AUG 2020 19:36

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 20:32
PC Open Date & Time	06 AUG 2020 20:31
PC Close Date & Time	07 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

Yes ☐	
PC Time stamp	07 AUG 2020 18:49
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

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

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

Yes ☐	
PC Time stamp	09 AUG 2020 22:00
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

Yes ☐	
PC Time stamp	10 AUG 2020 17:41
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

Yes ☐	
PC Time stamp	11 AUG 2020 23:58
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

Yes ☐	
PC Time stamp	13 AUG 2020 04:05
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	13 AUG 2020 21:31
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

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

ND PATIENT MOVED TO
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

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

ND PATIENT MOVED TO
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

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

ND PATIENT MOVED TO
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:39
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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	

US3452295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☐
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☒
Other ☐

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

10 SEP 2020

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

11:41 (24 HR)

Collection date and time (derived)

10 SEP 2020 11:41

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:12

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	10 SEP 2020 11:43
Nasopharyngeal Swab 2	No		

US3452295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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)	

US3452295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

11:25 (24 HR)

Collection date and time (derived)

2 OCT 2020 11:25

US3452295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 12:01:10

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 03:50:03

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 05:15:18

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 12:01:50

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 05:54:09

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 03:39:44
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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06 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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09 APR 2022 00:01

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13 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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23 APR 2022 00:01

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27 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

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04 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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01 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:12

Date of Contact	10 AUG 2020
Time of Contact	12:15
Date and Time of Contact (derived)	10 AUG 2020 12:15
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 ☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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)	308 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	312 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	316 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 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)	320 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	324 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 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)	328 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.4 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)	332 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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)	336 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	340 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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)	344 of 2538	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	348 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	352 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	356 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 AUG 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)	360 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	364 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)	368 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)	372 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	376 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 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)	380 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	384 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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)	388 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	31 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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)	392 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 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)	396 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 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)	400 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)	404 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

	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	☒

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)	408 of 2538	

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 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)	412 of 2538	

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

	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	☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

Date of Visit	10 AUG 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 AUG 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

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____ 16 /minute

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____ 95 BPM

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 _____ 95 %

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 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

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 _____

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

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

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:12

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:28:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 AUG 2020
Day 5	Yes	14 AUG 2020
Day 7	Yes	16 AUG 2020
Day 9	Yes	18 AUG 2020
Day 14	Yes	23 AUG 2020
Day 21	Yes	30 AUG 2020
Day 28	Yes	08 SEP 2020

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:23 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:23
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	254.7 lb
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3452295

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3452295

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 AUG 2020

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:35
Height (xxx.x)	71.0 in
Weight (xxx.x)	253.9 lb
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3452295

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:28:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 SEP 2020

US3452295

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

AEID

Adverse event

WORSENING OF ACID REFLUX

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)

07 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 AUG 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

13 AUG 2020 08:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

AEID	USA-US208-2020-MRNA-1273-P30 1000001
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)	06 AUG 2020
Start time (00:00-23:59)	16:40 (24 HR)
AE start date and time (derived)	06 AUG 2020 16:40
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

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	

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

PATIENT HAD SYMPTOMS OF
COVID 19 AND CALLED IN TO
THE CENTER. HE RETURNED
WITHIN 72 HOURS FOR ILLNESS
VISIT. SYMPTOMS AND
CONMEDS ARE LISTED ON
APPROPRIATE PAGES IN
SOURCE AND EDC. PATIENT
TESTED POSITIVE AT
SCREENING DATE 06-AUG-2020
AND RESULTS WERE RECEIVED
13-AUG-2020 AND AGAIN ON
10-AUG-2020. NO FURTHER
TESTING HAS BEEN DONE.
POSITIVE RESULT CONFIRMED
ON 17-AUG-2020. 1ST VACCINE
WAS RECEIVED ON
06-AUG-2020 HOWEVER THE
2ND VACCINE WILL NOT BE
GIVEN

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)	0

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:12

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

Yes ☒

No ☐

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

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HIGH BLOOD PRESSURE
Dose per administration	10
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 ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

	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 2015
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	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	PRILOSEC
Prophylaxis	Yes ☐ No ☒
Indication	HEARTBURN
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

	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 2015
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	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	CERTIRIZINE
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	10
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 ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

	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 2015
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	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	PEPCID
Prophylaxis	Yes ☐ No ☒
Indication	STOMACH COATING/ACID REFLUX
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 AUG 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	FLONASE
Prophylaxis	Yes ☐ No ☒
Indication	SINUS CONGESTION/ COVID 19
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	SQUIRT
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 ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

	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)		07 AUG 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	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	ZICAM (ZINC ACETATE AND ZINC GLUCONATE)
Prophylaxis	Yes ☐ No ☒
Indication	COUGH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		07 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 AUG 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	☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	BENZONATE
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☒ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	03 SEP 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	ALBUTEROL PRO AIR
Prophylaxis	Yes ☐ No ☒
Indication	CHEST CONGESTION/ COVID 19
Dose per administration	32
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 ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

	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)	07 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	13 SEP 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	☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

Name of Medication OMEGA 3 ACID
(ALPHA-LINOLENIC ACID,
EICOSAPENTAENOIC ACID,
AND DOCOSAHEXAENOIC ACID
)

Prophylaxis Yes ☒
No ☐

Indication IMMUNE HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

v6.020 DTW (1102)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 AUG 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

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

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

	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)		07 AUG 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	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

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

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

	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)		07 AUG 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	☒

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	AUGMENTIN/CLAVULANIC ACID
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF SINUSITIS
Dose per administration	825/125
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 ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

Name of Medication	AUGMENTIN/CLAVULANIC ACID
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF SINUSITIS
Dose per administration	875/125
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 ☐

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3452295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:12

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3452295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:12

Date of dosing discontinuation (dd MMM yyyy)

10 AUG 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

US3452295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:28:12

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 ☐

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Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

SAEID	USA-US208-2020-MRNA-1273-P301000001
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)	3

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:12

SAEID	USA-US208-2020-MRNA-1273-P301000001
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)	3
Date of submission (Pre-filled from custom function)	19/AUG/2020 09:40
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

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:12

SAEID	USA-US208-2020-MRNA-1273-P301000001
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)	3
Date of submission (Pre-filled from custom function)	28/AUG/2020 11:40
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

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:28:12

SAEID	USA-US208-2020-MRNA-1273-P301000001
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)	3
Date of submission (Pre-filled from custom function)	09/SEP/2020 22:07
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

US3452295 (Prod: Lynn Health Science Institute)

US3452295

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:12

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3452295'	RWS_ENDPOINT ENDPOINT (b) (4) 	06 Aug 2020 21:14:10

US3452295

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:09

US3452295

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	06 Aug 2020 21:14:11

US3452295

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:09

US3452295

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	06 Aug 2020 21:20:09

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 21:14:12

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Age](#)

Audit	User	Time (GMT)
User entered '62'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '63'	System	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[White](#)

Audit	User	Time (GMT)
User entered '1'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:12

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 21:14:11

US3452295

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:09

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
Data point term sent to Coder	System	06 Aug 2020 23:46:55
User entered 'SEASONAL ALLERGIES'	Kim Calloway (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
Data point term sent to Coder	System	06 Aug 2020 23:46:55
User entered 'HEARTBURN'	Kim Calloway (b) (4)	06 Aug 2020 23:46:44
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:49:01
Data point term sent to Coder	System	06 Aug 2020 23:47:55
User entered 'LOW TESTOSTERONE'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:49:01
Data point term sent to Coder	System	06 Aug 2020 23:47:55
User entered 'HIGH BLOOD PRESSURE'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 23:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 23:49:01
Data point term sent to Coder	System	06 Aug 2020 23:47:56
User entered 'SINUS SURGERY'	Kim Calloway (b) (4)	06 Aug 2020 23:47:50
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:50:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:50:02
Data point term sent to Coder	System	06 Aug 2020 23:48:57
User entered 'ALLERGY TO SULFA'	Kim Calloway (b) (4)	06 Aug 2020 23:48:05
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Reaction to food additive, LLT: Artificial sweetener intolerance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:53:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:53:04
Data point term sent to Coder	System	06 Aug 2020 23:48:56
User entered 'ALLERGY TO SACCHARIN'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'UN UNK 1975'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '1975'	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:32:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:32:19
Data point term sent to Coder	System	06 Oct 2020 16:31:10
User entered 'chronic sinusitis'	(b) (4), (b) (6) (b) (4)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'un UNK 1977'	(b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Jan 1977'	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '1977'	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '16:32'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:32'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '71' in	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
DataPoint set to visible.	(b) (4) System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '254.8' lb	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
DataPoint set to visible.	(b) (4) System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
Amendment Manager: User entered '35.61169'	System	16 Sep 2020 23:46:33
User entered '35.6'	System	13 Aug 2020 19:06:43
DataPoint set to visible.	System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	13 Aug 2020 19:06:43
DataPoint set to visible.	System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 06:55:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Oct 2020 04:39:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:57
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4)	01 Oct 2020 19:59:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 19:59:19
User entered 'NS' (non-conformant).	April Green (b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:05
User entered '98.3' F	Kim Calloway (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:57
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered 'Oral (Oral)'	Kim Calloway (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	April Green (b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '84'	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	April Green (b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '20'	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	April Green (b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '138'	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	April Green (b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '96'	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:49

US3452295

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 07:19:46
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 17:28:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	26 Aug 2020 23:42:00
Comment added 'DATE IS CORRECT'.	Kim Calloway (b) (4)	26 Aug 2020 12:02:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	18 Aug 2020 20:42:51
User entered '06 Aug 2020'	Kim Calloway (b) (4)	06 Aug 2020 21:20:49

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

Other

Audit	User	Time (GMT)
User entered '0'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:12

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:09

US3452295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:09

US3452295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:09

US3452295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	06 Aug 2020 21:21:09

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	06 Aug 2020 21:19:15

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:43:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:43:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 21:19:15
User entered '101810' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 21:19:15

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	06 Aug 2020 21:19:15

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:18

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:18

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:18

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:18

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:12

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:18

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:26:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:26
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4)	01 Oct 2020 20:00:09
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:27
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:26
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:26:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:26
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4)	01 Oct 2020 20:00:09
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:27
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:26
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	02 Oct 2020 04:39:06
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 04:39:06
User entered '06 Aug 2020' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 04:39:06
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	01 Oct 2020 20:01:04
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Oct 2020 20:01:04
User entered '06 Aug 2010' reason for change: Data Entry Error	April Green (b) (4) (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '16:32' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:32'	System	02 Oct 2020 04:39:06
User entered '06 Aug 2010 16:32'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '98.3' F reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '20' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:26:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:26
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4)	01 Oct 2020 20:00:09
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:27
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:12

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:26
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 18:13:18
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 19:08:16
User entered '17:26'	Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 17:26'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '15'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '135'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '91'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:28

US3452295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:21:28

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:46'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:46'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:40'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:40'	System	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '16:37'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:37'	System	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4)	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '16:37'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:37'	System	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User		Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kim Calloway (b) (4)	(b) (4)	13 Aug 2020 19:16:51
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4)	(b) (4)	13 Aug 2020 19:16:35
User entered 'Yes (Y)'	Kim Calloway (b) (4)	(b) (4)	06 Aug 2020 21:21:36

US3452295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:16:51
User entered empty.	System	13 Aug 2020 19:16:35
User entered '1'	System	06 Aug 2020 21:21:36

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64'	System	06 Aug 2020 22:22:51
User entered 'Yes (Y)'	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:35', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64'	System	06 Aug 2020 22:22:51
User entered '98.2'	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:39', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64'	System	06 Aug 2020 22:22:51
User entered 'No (N)'	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64'	System	06 Aug 2020 22:22:51
User entered '06 Aug 2020 17:22'	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 17:06'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 19:36'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b'	System	07 Aug 2020 01:31:48
User entered 'Yes (Y)'	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b'	System	07 Aug 2020 01:31:48
User entered '97.5'	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:37', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b'	System	07 Aug 2020 01:31:48
User entered 'No (N)'	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b'	System	07 Aug 2020 01:31:48
User entered '06 Aug 2020 20:31'	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 20:31'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 2'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered 'Yes (Y)'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered '99.9'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered 'Yes (Y)'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:25:46
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4)	27 Aug 2020 11:42:10
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).	(b) (4), (b) (6)	17 Aug 2020 15:33:18
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:33:13
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 'Added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:27:47
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).	System	07 Aug 2020 23:45:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered '1'	System	07 Aug 2020 23:45:42
v6.020 DTW (1102)		719 of 2538

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered '0'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered '07 Aug 2020 18:45'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 3'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:12', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f'	System	09 Aug 2020 05:35:43
User entered 'Yes (Y)'	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f'	System	09 Aug 2020 05:35:43
User entered '100.5'	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:24', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f'	System	09 Aug 2020 05:35:43
User entered 'Yes (Y)'	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:25:51
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:21
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:33:32
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).	(b) (4), (b) (6)	17 Aug 2020 15:33:24
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 'added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:27:58
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).	System	09 Aug 2020 05:35:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f'	System	09 Aug 2020 05:35:43
User entered '1'	System	09 Aug 2020 05:35:43
v6.020 DTW (1102)		728 of 2538

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f'	System	09 Aug 2020 05:35:43
User entered '0'	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:42', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f'	System	09 Aug 2020 05:35:43
User entered '09 Aug 2020 00:35'	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 4'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered 'Yes (Y)'	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:47', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered '97.7'	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:51', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered 'Yes (Y)'	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:25:55
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:34
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:33:53
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).	(b) (4), (b) (6)	17 Aug 2020 15:33:38
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 'added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:28:07
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).	System	10 Aug 2020 02:58:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered '1'	System	10 Aug 2020 02:58:04
v6.020 DTW (1102)		737 of 2538

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered '0'	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:02', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered '09 Aug 2020 21:58'	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 5'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:14', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8'	System	10 Aug 2020 22:40:52
User entered 'Yes (Y)'	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:21', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '98.3'	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8'	System	10 Aug 2020 22:40:52
User entered 'Yes (Y)'	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '0'	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:26:04
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:48
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:34:05
User closed query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	17 Aug 2020 15:34:00
Query 'Per the participant response, medication was taken to prevent 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 'added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:28:15
User opened query 'Per the participant response, medication was taken to prevent 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).	System	10 Aug 2020 22:40:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '1'	System	10 Aug 2020 22:40:52
v6.020 DTW (1102)		747 of 2538

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8'	System	10 Aug 2020 22:40:52
User entered '10 Aug 2020 17:40'	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 6'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:07', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered 'Yes (Y)'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered '98.0'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered 'Yes (Y)'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:24', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered '0'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 19:26:10
User opened query 'Per the participant response, medication was taken to prevent 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).	Kim Calloway (b) (4)	27 Aug 2020 11:43:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:24', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered '1'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:29', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered '11 Aug 2020 23:57'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 7'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	System	13 Aug 2020 09:04:24
User entered 'Yes (Y)'	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:11', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	System	13 Aug 2020 09:04:24
User entered '98.0'	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:15', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	System	13 Aug 2020 09:04:24
User entered 'Yes (Y)'	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:19', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	System	13 Aug 2020 09:04:24
User entered '0'	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 19:26:14
User opened query 'Per the participant response, medication was taken to prevent 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).	Kim Calloway (b) (4)	27 Aug 2020 11:43:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:19', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	System	13 Aug 2020 09:04:24
User entered '1'	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:22', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	System	13 Aug 2020 09:04:24
User entered '13 Aug 2020 04:04'	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 04:57:33
User entered 'Day 8'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11'	System	14 Aug 2020 02:31:48
User entered 'Yes (Y)'	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:39', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11'	System	14 Aug 2020 02:31:48
User entered '97.8'	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11'	System	14 Aug 2020 02:31:48
User entered 'No (N)'	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11'	System	14 Aug 2020 02:31:48
User entered '13 Aug 2020 21:31'	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:56', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def'	System	06 Aug 2020 22:23:16
User entered 'None (1)'	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:01', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def'	System	06 Aug 2020 22:23:16
User entered 'No (N)'	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:05', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def'	System	06 Aug 2020 22:23:16
User entered 'No (N)'	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def'	System	06 Aug 2020 22:23:16
User entered 'None (1)'	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:13', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def'	System	06 Aug 2020 22:23:16
User entered '06 Aug 2020 17:23'	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 17:06'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 19:36'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:56', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc'	System	07 Aug 2020 01:32:19
User entered 'None (1)'	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:02', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc'	System	07 Aug 2020 01:32:19
User entered 'No (N)'	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:06', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc'	System	07 Aug 2020 01:32:19
User entered 'No (N)'	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc'	System	07 Aug 2020 01:32:19
User entered 'None (1)'	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:15', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc'	System	07 Aug 2020 01:32:19
User entered '06 Aug 2020 20:32'	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 20:31'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 2'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:49', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2'	System	07 Aug 2020 23:48:14
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2'	System	07 Aug 2020 23:48:14
User entered 'No (N)'	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:59', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2'	System	07 Aug 2020 23:48:14
User entered 'Yes (Y)'	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:47:53', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2' User entered '30'	System	07 Aug 2020 23:48:14
	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:47:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2'	System	07 Aug 2020 23:48:14
User entered 'None (1)'	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:13', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2'	System	07 Aug 2020 23:48:14
User entered '07 Aug 2020 18:48'	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 3'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:51', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d'	System	09 Aug 2020 05:36:09
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d'	System	09 Aug 2020 05:36:09
User entered 'No (N)'	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d'	System	09 Aug 2020 05:36:09
User entered 'No (N)'	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d'	System	09 Aug 2020 05:36:09
User entered 'None (1)'	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d'	System	09 Aug 2020 05:36:09
User entered '09 Aug 2020 00:36'	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 4'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b'	System	10 Aug 2020 02:58:29
User entered 'None (1)'	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:12', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b'	System	10 Aug 2020 02:58:29
User entered 'No (N)'	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:15', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b'	System	10 Aug 2020 02:58:29
User entered 'No (N)'	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:23', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b'	System	10 Aug 2020 02:58:29
User entered 'None (1)'	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b'	System	10 Aug 2020 02:58:29
User entered '09 Aug 2020 21:58'	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 5'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered 'None (1)'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered 'No (N)'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:01', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered 'No (N)'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:05', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered 'None (1)'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered '10 Aug 2020 17:41'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 6'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13'	System	12 Aug 2020 04:57:47
User entered 'None (1)'	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13'	System	12 Aug 2020 04:57:47
User entered 'No (N)'	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:39', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13'	System	12 Aug 2020 04:57:47
User entered 'No (N)'	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:42', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13'	System	12 Aug 2020 04:57:47
User entered 'None (1)'	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13'	System	12 Aug 2020 04:57:47
User entered '11 Aug 2020 23:57'	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 7'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'None (1)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'No (N)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'No (N)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'None (1)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:44', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered '13 Aug 2020 04:04'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:22', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'None (0)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'None (0)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:29', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'None (0)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:32', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'None (0)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'None (0)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'None (0)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered 'No (N)'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9'	System	06 Aug 2020 22:23:49
User entered '06 Aug 2020 17:23'	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 17:06'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 19:36'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:22', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'None (0)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'None (0)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:32', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'None (0)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:38', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'None (0)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'None (0)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'None (0)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:49', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered 'No (N)'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830'	System	07 Aug 2020 01:33:05
User entered '06 Aug 2020 20:32'	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 20:31'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 2'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'Some interference with activity (2)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:45', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'None (0)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'None (0)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:53', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'None (0)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:49:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered 'No (N)'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:49:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f'	System	07 Aug 2020 23:49:06
User entered '07 Aug 2020 18:49'	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 3'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:18', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'None (0)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:23', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:29', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acc3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'None (0)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'No interference with activity (1)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:52', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'No (N)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered '09 Aug 2020 00:36'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 4'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'None (0)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:23', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:28', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'None (0)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:32', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'None (0)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:42', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:50', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No (N)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T22:00:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered '09 Aug 2020 22:00'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 5'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'None (0)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'No interference with activity (1)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'No interference with activity (1)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'None (0)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'None (0)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'Some interference with activity not requiring medical attention (2)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'No (N)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:49', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered '10 Aug 2020 17:41'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 6'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:51', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'None (0)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'No interference with activity (1)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:59', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'No interference with activity (1)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:02', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'None (0)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'None (0)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'None (0)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:14', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'No (N)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered '11 Aug 2020 23:58'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 7'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:50', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'None (0)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:52', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'None (0)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'None (0)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'None (0)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'None (0)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'None (0)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:07', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'No (N)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:11', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered '13 Aug 2020 04:05'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 04:57:33
User entered 'Day 8'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:12

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:52', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '7fb722fe-b83e-4d8a-a202-7e39cf19b2f4'	System	14 Aug 2020 02:31:59
User entered 'No (N)'	System	14 Aug 2020 02:31:59

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:12

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '7fb722fe-b83e-4d8a-a202-7e39cf19b2f4'	System	14 Aug 2020 02:31:59
User entered '13 Aug 2020 21:31'	System	14 Aug 2020 02:31:59

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 04:57:33

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered 'ND Patient moved to Convalescent Period'	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:29:45

US3452295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:29:45

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered 'ND Patient moved to Convalescent Period'	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:52:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:29:54

US3452295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:29:54

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'ND Patient moved to Convalescent Period'	(b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:30:04

US3452295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:30:04

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '11:39'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:39'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '20'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '148'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '84'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:31:17

US3452295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:31:17

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Since the subject has discontinued from the IP dosing. Please review and update the Dosing Discontinuation form under End of study visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:29:58
Query 'Per CDM: Since the subject has discontinued from the IP dosing. Please review and update the Dosing Discontinuation form under End of study visit. Thank you.' answered with 'UPDATED' (Site from DM).	Kim Calloway (b) (4)	07 Oct 2020 17:17:12
User opened query 'Per CDM: Since the subject has discontinued from the IP dosing. Please review and update the Dosing Discontinuation form under End of study visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:56:05
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Confirmed COVID-19 (COVID)'	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:41'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:41'	System	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '11:43'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:43'	System	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:31:25

US3452295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:31:25

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:32:05

US3452295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:32:05

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:57:21

US3452295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 14:57:21

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:00:55

US3452295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 17:00:55

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered empty.	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:35

US3452295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:01:35

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:25'	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020 11:25'	System	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	05 Nov 2020 14:42:57

US3452295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 14:42:57

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 71'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-15T12:01:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '287940a8-599a-4a78-b411-b1d9463f726f' User entered 'No (N)'	System	15 Oct 2020 17:01:30
	System	15 Oct 2020 17:01:30

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-15T12:01:05', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '287940a8-599a-4a78-b411-b1d9463f726f' User entered 'No (N)'	System	15 Oct 2020 17:01:30
	System	15 Oct 2020 17:01:30

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-15T12:01:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '287940a8-599a-4a78-b411-b1d9463f726f' User entered '15 Oct 2020 12:01:10'	System	15 Oct 2020 17:01:30
	System	15 Oct 2020 17:01:30

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 78'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-24T03:49:47', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1dc670b0-49a0-4c10-92d3-b03a4b79261f' User entered 'No (N)'	System	24 Oct 2020 08:50:08
	System	24 Oct 2020 08:50:08

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-24T03:49:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1dc670b0-49a0-4c10-92d3-b03a4b79261f' User entered 'No (N)'	System	24 Oct 2020 08:50:08
	System	24 Oct 2020 08:50:08

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-24T03:50:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1dc670b0-49a0-4c10-92d3-b03a4b79261f' User entered '24 Oct 2020 03:50:03'	System	24 Oct 2020 08:50:08
	System	24 Oct 2020 08:50:08

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 92'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-03T05:15:09', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'fd8b7971-06da-408e-bb75-7b046d6aa974'	System	03 Nov 2020 11:15:22
User entered 'No (N)'	System	03 Nov 2020 11:15:22

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-03T05:15:14', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'fd8b7971-06da-408e-bb75-7b046d6aa974'	System	03 Nov 2020 11:15:22
User entered 'No (N)'	System	03 Nov 2020 11:15:22

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-03T05:15:18', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'fd8b7971-06da-408e-bb75-7b046d6aa974'	System	03 Nov 2020 11:15:22
User entered '03 Nov 2020 05:15:18'	System	03 Nov 2020 11:15:22

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 99'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-12T12:01:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c7f12d1a-8f75-43ca-a097-29756e6fa819'	System	12 Nov 2020 18:01:54
User entered 'No (N)'	System	12 Nov 2020 18:01:54

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-12T12:01:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c7f12d1a-8f75-43ca-a097-29756e6fa819'	System	12 Nov 2020 18:01:54
User entered 'No (N)'	System	12 Nov 2020 18:01:54

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-12T12:01:50', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c7f12d1a-8f75-43ca-a097-29756e6fa819' User entered '12 Nov 2020 12:01:50'	System	12 Nov 2020 18:01:54
	System	12 Nov 2020 18:01:54

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 106'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-17T05:53:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd418b29a-8810-4f1a-bde1-f3128d921ffe'	System	17 Nov 2020 11:55:48
User entered 'No (N)'	System	17 Nov 2020 11:55:48

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-17T05:54:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd418b29a-8810-4f1a-bde1-f3128d921ffe'	System	17 Nov 2020 11:55:48
User entered 'No (N)'	System	17 Nov 2020 11:55:48

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-17T05:54:09', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd418b29a-8810-4f1a-bde1-f3128d921ffe' User entered '17 Nov 2020 05:54:09'	System	17 Nov 2020 11:55:48
	System	17 Nov 2020 11:55:48

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Oct 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Oct 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-24T03:39:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75406c8-7d6b-461f-a30c-65fbcaec0a76'	System	24 Nov 2020 09:39:47
User entered 'No (N)'	System	24 Nov 2020 09:39:47

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-24T03:39:37', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75406c8-7d6b-461f-a30c-65fbcaec0a76'	System	24 Nov 2020 09:39:47
User entered 'No (N)'	System	24 Nov 2020 09:39:47

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-24T03:39:44', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75406c8-7d6b-461f-a30c-65fbcaec0a76'	System	24 Nov 2020 09:39:47
User entered '24 Nov 2020 03:39:44'	System	24 Nov 2020 09:39:47

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Chalimar Rojo (b) (4) (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4) (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:12

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:12

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered '12:15' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 20:44:23
User entered '12:30'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:15'	System	18 Aug 2020 20:44:23
User entered '10 Aug 2020 12:30'	System	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:12

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (10AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:56:39
Query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (10AUG2020) or update accordingly' answered with 'correct' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:27:59
User opened query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (10AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:31:15
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '11 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.5' F	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '12 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '13 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.8' F	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:10:12
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:10:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '14 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '15 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.8' F	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
User closed query 'Per source, sore throat is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:11:10
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:08
Query 'Per source, sore throat is indicated as 'mild'. Please reconcile' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:04:55
User opened query 'Per source, sore throat is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:10:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:09:53
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '16 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.4' F	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '17 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:30:15
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:34:36
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:33:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:33:30
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:30:15
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Aug 2020 15:33:30
User entered empty.	System	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:59
User closed query 'Per source, body aches is graded as 'none'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:11:57
Query 'Per source, body aches is graded as 'none'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:05:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:05:30
User opened query 'Per source, body aches is graded as 'none'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:18:06
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:19
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '23 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.1' F	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:12:13
User closed query 'Per source, O2 saturation is listed as '97%'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:12
Query 'Per source, O2 saturation is listed as '97%'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:06:45
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:06:38
User opened query 'Per source, O2 saturation is listed as '97%'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:12:19
User closed query 'Per source, temperature is listed as '98.0 F'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:16
Query 'Per source, temperature is listed as '98.0 F'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:06:50
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:06:38
User opened query 'Per source, temperature is listed as '98.0 F'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:21:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:20:25
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '26 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.1' F	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '27 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.9' F	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:12:40
User closed query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:39
Query 'Please indicate whether diarrhea was present. ' answered with 'entered ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:11:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:11:39
User opened query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:23:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:23:21
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:12:45
User closed query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:43
Query 'Please indicate whether diarrhea was present. ' answered with 'entered' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:11:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:11:39
User opened query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:24:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:23:23
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '30 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 22 (Day 22)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '31 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '95'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 23 (Day 23)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '01 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:16:13
User entered '97.' (non-conformant).	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 16:16:13
User entered empty.	System	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:13:08
User closed query 'Per source, temperature is listed as '97.8'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:06
Query 'Per source, temperature is listed as '97.8'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:12:36
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:12:29
User opened query 'Per source, temperature is listed as '97.8'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:27:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:26:18
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:16:13
User entered '98' F	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 24 (Day 24)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '02 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.3' F	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 25 (Day 25)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 26 (Day 26)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:13:23
User closed query 'Per source, headache is indicated as 'mild'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:21
Query 'Per source, headache is indicated as 'mild'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:13:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:13:05
User opened query 'Per source, headache is indicated as 'mild'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:30:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:29:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:13:28
User closed query 'Per source, nasal congestion is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:26
Query 'Per source, nasal congestion is indicated as 'mild'. Please reconcile' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:13:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:13:05
User opened query 'Per source, nasal congestion is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:30:42
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:20
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:51:22
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 27 (Day 27)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:19:39
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08SEP2020. Please reconcile or clarify.' answered with 'information is correcte due to the holiday day 28 was oushed out' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:29:13
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:31:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '05 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.9' F	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:28:12

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
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)	21 Aug 2020 13:44:58
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'entered' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 20:40:35
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	18 Aug 2020 20:40:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User closed query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	System	21 Aug 2020 14:18:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:18:28
User opened query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	System	18 Aug 2020 20:40:25
User entered 'Done at clinic visit'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
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	21 Aug 2020 14:18:52
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	21 Aug 2020 14:18:37
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:18:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:18:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:18:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:18:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:18:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:18:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:12

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered '16'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:28:12

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:52:21
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:52

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '12 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '14 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '16 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 21:03:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 21:03:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 21:03:36
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:47:18
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 21:03:36
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:09:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 16:09:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:09:56
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:47:18
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '30 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:09:56
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:28:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:28:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:28:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 17:28:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:28:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:47:18
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:13:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:53
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:28:10
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:46:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please reconcile and confirm date of Illness Visit D1 and procedures according to data in Preclarus Lab Portal' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:33:40
Query 'Per ETRTR: Please reconcile and confirm date of Illness Visit D1 and procedures according to data in Preclarus Lab Portal' answered with 'Illness visit was performed on 10-AUG-2020 lab portal is incorrect and has been notified to correct ' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 21:12:52
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:46:46
User opened query 'Per ETRTR: Please reconcile and confirm date of Illness Visit D1 and procedures according to data in Preclarus Lab Portal' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 22:27:24
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:46:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '12:23'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:23'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '71' in	(b) (4), (b) (6)	18 Aug 2020 20:43:59
DataPoint set to visible.	System	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '254.7' lb	(b) (4), (b) (6)	18 Aug 2020 20:43:59
DataPoint set to visible.	System	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '98.2' F	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User closed query 'per ETRTR: Please confirm clinical significance on Pulse, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 21:47:18
Query 'per ETRTR: Please confirm clinical significance on Pulse, thanks.' answered with 'NSC' (Site from CRA).	Kim Calloway (b) (4) (b) (4)	24 Aug 2020 15:42:02
User opened query 'per ETRTR: Please confirm clinical significance on Pulse, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 21:54:58
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '16'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User closed query 'Response is noted, however, please indicate CS/NCS' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 06:48:23
Query 'Response is noted, however, please indicate CS/NCS' answered with 'NCS' (Site from DM).	Kim Calloway (b) (4)	24 Aug 2020 15:42:10
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:14:02
User opened query 'Response is noted, however, please indicate CS/NCS' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 19:14:00
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Information is correct' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 20:44:09
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Aug 2020 20:43:59
User entered '159'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:45:41

US3452295

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:34
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:45:41

US3452295

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:46:33

US3452295

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:47:40
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:46:33

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:12:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:14
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:32
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:12:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:24
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '11:35'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:35'	System	10 Nov 2020 17:20:24
User entered '8 Sep 2020 11:35'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '71.0' in	(b) (4), (b) (6)	08 Sep 2020 17:37:05
DataPoint set to visible.	System	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '253.9' lb	(b) (4), (b) (6)	08 Sep 2020 17:37:05
DataPoint set to visible.	System	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '98.5' F	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '72'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '14'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '139'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '93'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:28:36

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:12

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:25:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:33
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:33
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:54:56
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:28:36

US3452295

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:28:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:55:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:28:55

US3452295

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:28:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:12:53
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:42
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:42
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:55:04
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:28:55

US3452295

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:57
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:25

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please review and update the severity. If the AE is worsening of a concurrent Medical History condition, then the severity of the AE should be greater than mild. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:41:11
Query 'Per MM, Please review and update the severity. If the AE is worsening of a concurrent Medical History condition, then the severity of the AE should be greater than mild. ' answered with 'SUBJECT REPORTED WORSENING WAS MILD' (Site from DM).	Kim Calloway (b) (4)	07 Oct 2020 19:32:51
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User opened query 'Per MM, Please review and update the severity. If the AE is worsening of a concurrent Medical History condition, then the severity of the AE should be greater than mild. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:33:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 21:49:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 21:49:49
Data point term sent to Coder	System	21 Sep 2020 21:49:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
Data point term sent to Coder	System	21 Sep 2020 21:45:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 12:15:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 12:15:25
Data point term sent to Coder	System	18 Aug 2020 18:24:53

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Worsening of ACID REFLUX' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:46:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:46:13
Data point term sent to Coder	System	13 Aug 2020 19:45:47
User entered 'ACID REFLUX'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Sep 2020 12:57:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'corrected' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 21:44:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:43:58
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	09 Sep 2020 14:08:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 18:10:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:10:44
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:07:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:07:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:13:22
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per your previous response "unknown". However, the Event started 7Aug2020 just after the day of dosing 06Aug2020. Please confirm if the event started within 24 hrs of dosing then update a best estimated time or confirm in the response if the event started after 24 hrs of the Dosing. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:41:05
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Per CDM: Per your previous response "unknown". However, the Event started 7Aug2020 just after the day of dosing 06Aug2020. Please confirm if the event started within 24 hrs of dosing then update a best estimated time or confirm in the response if the event started after 24 hrs of the Dosing. Thank you.' answered with 'TIME IS UNKNOWN' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:15:53
User opened query 'Per CDM: Per your previous response "unknown". However, the Event started 7Aug2020 just after the day of dosing 06Aug2020. Please confirm if the event started within 24 hrs of dosing then update a best estimated time or confirm in the response if the event started after 24 hrs of the Dosing. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:29:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Per CDM, please confirm that Adverse Event started exactly in midnight (00:00), otherwise amend where applicable.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:33:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 11:33:08
Query 'Per CDM, please confirm that Adverse Event started exactly in midnight (00:00), otherwise amend where applicable.' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:10:58
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 18:08:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:07:40

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:07:40
User opened query 'Per CDM, please confirm that Adverse Event started exactly in midnight (00:00), otherwise amend where applicable.' (Site from DM). User entered '00:00'	(b) (4), (b) (6) Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:13:27 13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	System	08 Sep 2020 18:07:40
User entered '07 Aug 2020 00:00'	System	18 Aug 2020 18:13:22
User entered '06 Aug 2020 00:00'	System	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '08:00' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '13 Aug 2020 08:00'	System	18 Aug 2020 18:23:55
User entered empty.	System	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1/Mild. Please confirm/update the severity or delete the AE if unchanged from baseline.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:04:34
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1/Mild. Please confirm/update the severity or delete the AE if unchanged from baseline.' answered with 'It has a mild worsening. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 22:01:59
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1/Mild. Please confirm/update the severity or delete the AE if unchanged from baseline.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:44:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Not Related (NOT RELATED)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Not Related (NOT RELATED)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'None (NONE)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '1'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Form: Adverse Events (4)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:03
User entered 'USA-US208-2020-mRNA-1273-P301000001'	System	19 Aug 2020 13:39:54
User entered 'New'	(b) (4), (b) (6)	19 Aug 2020 13:39:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:49:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:49:49
Data point term sent to Coder	System	21 Sep 2020 21:49:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
Data point term sent to Coder	System	21 Sep 2020 21:45:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
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)	18 Aug 2020 19:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:01:06
Data point term sent to Coder	System	18 Aug 2020 17:47:20
User entered 'COVID-19'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 20:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 20:53:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 20:53:01
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 13:55:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 13:55:30
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'PV Query: Please confirm that the patient tested positive for COVID-19 on 06 Aug 2020 or provide the signs/symptoms the subject experienced on this date. If the subject did not test positive on 06 Aug and was not experiencing any symptoms on this date, please consider updating event start date.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:38:51
Query 'PV Query: Please confirm that the patient tested positive for COVID-19 on 06 Aug 2020 or provide the signs/symptoms the subject experienced on this date. If the subject did not test positive on 06 Aug and was not experiencing any symptoms on this date, please consider updating event start date.' answered with 'Patient tested positive at screening on 06-AUG-2020' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:54:22
User opened query 'PV Query: Please confirm that the patient tested positive for COVID-19 on 06 Aug 2020 or provide the signs/symptoms the subject experienced on this date. If the subject did not test positive on 06 Aug and was not experiencing any symptoms on this date, please consider updating event start date.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:55:14
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:36:17
User entered '13 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 18:37:31
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:37:31
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 18:36:17
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 17:47:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 17:47:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 17:47:04
User entered '12:00'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '06 Aug 2020 16:40'	System	18 Aug 2020 18:37:31
User entered empty.	System	18 Aug 2020 17:47:24
User entered '13 Aug 2020 12:00'	System	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	08 Sep 2020 18:16:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:16:30
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	08 Sep 2020 18:14:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Form: Adverse Events (5)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'PV Query: Please provide the event end date (the end date of COVID-19 symptoms).' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:16
Query 'PV Query: Please provide the event end date (the end date of COVID-19 symptoms).' answered with 'entered' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:14:42
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please provide the event end date (the end date of COVID-19 symptoms).' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:03:11
User closed query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:38:58
Query 'PV Query: Please provide the event end date.' answered with 'Are you wanting an end date for symptoms or for a negative test result?' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:59:47
User opened query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:54:24
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 11:21:37
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 18:16:43
User opened query 'Data is required. Please provide.' System (Site from System).		08 Sep 2020 18:16:30
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	System	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:13:02
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Deleted' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 17:47:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Aug 2020 17:47:04
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response to this data point needs to be recorded if the subject has "Requires inpatient or prolongation of existing Hospitalization" marked as yes. Since the event is not and SAE, please verify and amend the data as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:41:38
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Per CDM: Response to this data point needs to be recorded if the subject has "Requires inpatient or prolongation of existing Hospitalization" marked as yes. Since the event is not and SAE, please verify and amend the data as appropriate. Thank you.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:17:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 02:17:41
User opened query 'Per CDM: Response to this data point needs to be recorded if the subject has "Requires inpatient or prolongation of existing Hospitalization" marked as yes. Since the event is not and SAE, please verify and amend the data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:06:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:27:10
Reviewed for Data Management.	(b) (4), (b) (6)	23 Sep 2020 08:46:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 21:44:46
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 21:44:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:44:46
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:14:26
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

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)	28 Oct 2020 13:58:05
User closed query 'Per CDM requery: Per your response. Please update the data under END of Study visit Dosing Discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:43:06
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 '	Kim Calloway (b) (4)	07 Oct 2020 19:33:59

COORDINATOR WAS TOLD TO FILL OUT THIS WAY DUE TO PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND RESULTS WERE RECEIVED 13-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE REULT CONFIRMED ON 17-AUG-2020. 1ST VACCINE WAS RECEIVED ON 06-AUG-2020 HOWEVER THE 2ND VACCINE WILL NOT BE GIVEN' (Site from System).

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	07 Oct 2020 19:32:18

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).	System	07 Oct 2020 19:30:07

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Folder: Adverse Events

Form: Adverse Events (5)

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Action taken with investigational product

Audit	User	Time (GMT)
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 by data change (Site from System). DataPoint Verified.	System (b) (4), (b) (6)	07 Oct 2020 19:30:07 07 Oct 2020 17:46:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	07 Oct 2020 17:16:50
Query 'Per CDM query: Per your response. Please update the data under END of Study visit Dosing Discontinuation form. Thank you.' answered with 'MEDICATION IS LISTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:18:56
User opened query 'Per CDM query: Per your response. Please update the data under END of Study visit Dosing Discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:10:27
User closed query 'Per CDM: Action Taken is recorded as 'Investigational Product Withdrawn', however Dosing Discontinuation page has not been completed. Please enter page.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:10:27
Query 'Per CDM: Action Taken is recorded as 'Investigational Product Withdrawn', however Dosing Discontinuation page has not been completed. Please enter page.' answered with 'Where is the dosing discontinuation page' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 22:03:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User opened query 'Per CDM: Action Taken is recorded as 'Investigational Product Withdrawn', however Dosing Discontinuation page has not been completed. Please enter page.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:00:19
User closed 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)	10 Sep 2020 02:23:11

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
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 'pt will not receive 2nd vaccine' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:15:24
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
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)	02 Sep 2020 14:04:27
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:57:19
Query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'SEE CONMEDS' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:52:30
User opened query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:45:08
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:45:08
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'MEDICATION HAS BEEN LISTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:19:07

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:46:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '1'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:25
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'this is entered' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:17:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:54:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Per ETRTR: COVID + Narrative should describe clinical presentation/course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:35:29
User closed query 'PV Query: Please confirm the study drug was administered prior to positive test result being available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:30
User closed query 'PV Query: Thank you for confirming the nasopharyngeal swab from 06 Aug 2020 (screening) was positive. Please provide the date the results came back positive.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:27
Query 'PV Query: Please confirm the study drug was administered prior to positive test result being available.' answered with 'confirmed and updated' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:19:28
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND RESULTS WERE RECEIVED 13-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE RESULT CONFIRMED ON 17-AUG-2020. 1st vaccine was received on 06-Aug-2020 however the 2nd vaccine will not be given' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:19:17
Query 'PV Query: Thank you for confirming the nasopharyngeal swab from 06 Aug 2020 (screening) was positive. Please provide the date the results came back positive.' answered with 'added' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:18:23

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 and results were received 13-Aug-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE REULT CONFIRMED ON 17-AUG-2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:18:15
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. Positive reult confirmed on 17-AUG-2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please confirm the study drug was administered prior to positive test result being available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:03:52
User opened query 'PV Query: Thank you for confirming the nasopharyngeal swab from 06 Aug 2020 (screening) was positive. Please provide the date the results came back positive.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:03:39
User closed query 'PV Query: Please confirm dates of all COVID-19 swabs, as well as timing of vaccination.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:39:25
User closed query 'PV Query: Please provide the nasopharyngeal swab results from 06 Aug.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:39:11
Query 'PV Query: Please confirm dates of all COVID-19 swabs, as well as timing of vaccination.' answered with 'entered' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. Patient tested positive at screening date 06-Aug-2020 and again on 10-Aug-2020. No further testing has been done'	(b) (4), (b) (6)	27 Aug 2020 20:58:38
reason for change: Data Entry Error		
Query 'PV Query: Please provide the nasopharyngeal swab results from 06 Aug.' answered with 'Positive ' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:56:51
Query 'Per ETRTR: COVID + Narrative should describe clinical presentation/course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' answered with 'Added' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 20:56:36
User entered 'Patient had symptoms of covid 19 and called in to the center. He returned within 72 hours for illness visit. Symptoms and conmeds are listed on appropriate pages in source and EDC' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 20:56:11
User opened query 'PV Query: Please confirm dates of all COVID-19 swabs, as well as timing of vaccination.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:55:25
User opened query 'PV Query: Please provide the nasopharyngeal swab results from 06 Aug.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:54:53
User opened query 'Per ETRTR: COVID + Narrative should describe clinical presentation/course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 22:13:16
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '1'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:28:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:36
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:06

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
Data point term sent to Coder	System	13 Aug 2020 18:59:46
User entered 'LISINOPRIL'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'HIGH BLOOD PRESSURE'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '10'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:22:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:58:55
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:58:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
Data point term sent to Coder	System	13 Aug 2020 18:59:46
User entered 'PRILOSEC'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'HEARTBURN'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '20'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:22:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:59:30
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:29:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:29:45
Data point term sent to Coder	System	22 Oct 2020 12:28:30
Coding entries removed.	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:28:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:15:18
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 Aug 2020 22:15:18
Data point term sent to Coder	System	13 Aug 2020 19:00:49
User entered 'CERTIRIZINE'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:01:49
Query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' answered with ' ' (Site from DM).	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:28:17
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:28:12
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	22 Oct 2020 12:28:12
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:58:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'ALLERGIES'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '10'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:22:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:00:21
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 06:54:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 06:54:21
Data point term sent to Coder	System	19 Oct 2020 13:49:43
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 13:49:22
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:31:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:31:16
Data point term sent to Coder	System	13 Aug 2020 19:22:51
User entered 'PEPCID'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:03:58
	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:49:46
	(b) (4), (b) (6)	19 Oct 2020 13:49:22
User entered 'STOMACH COATING/ACID REFLUX' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:49:22
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 10:14:16
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'STOMACH COATING'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '40'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:08:31
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:50:34
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 13:50:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 13:50:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:50:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 13:50:07
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:50:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:50:07
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 10:14:33
User entered 'Yes (Y)'	Kim Calloway (b) (4)	07 Oct 2020 17:47:05
	(b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:36:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:36:38
Data point term sent to Coder	System	19 Oct 2020 13:51:44
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 13:51:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 22:48:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 22:48:53
Data point term sent to Coder	System	13 Aug 2020 19:23:55
User entered 'FLONASE'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:51:14
User entered 'SINUS CONGESTION/ COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:51:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'SINUS CONGESTION'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '1'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Other (OTHER)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'SQUIRT'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Nasal (NASAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:30:51
Query 'Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query.' answered with 'Patient has had ongoing sinusitis and medication is continuing. will update if it changes' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:20:24
User opened query 'Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:05:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:05:41
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:51:34
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:13:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	28 Oct 2020 14:04:13
	(b) (4), (b) (6) (b) (4)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with '.' (Site from DM). DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:27
	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:21
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:21
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Oct 2020 10:13:19
	(b) (4), (b) (6) (b) (4)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:35:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:35:44
Data point term sent to Coder	System	25 Aug 2020 18:10:05
User closed query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	25 Aug 2020 18:09:17
Query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'updated' (Site from System).	Kim Calloway (b) (4) (b) (4)	25 Aug 2020 18:09:17
User entered 'ZICAM (zinc acetate and zinc gluconate)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	25 Aug 2020 18:09:12
Data point term sent to Coder	System	24 Aug 2020 17:23:02
User entered 'ZICAM' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	24 Aug 2020 17:22:34
User opened query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4) (b) (4)	16 Aug 2020 12:26:07
Data point term sent to Coder	System	13 Aug 2020 19:25:01
User entered 'ZYCAM'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:43:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:24:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:09:37
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'COUGH'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '1'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'tablet (TABLET)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'as needed (PRN)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020' reason for change: Data Entry Error	Kim Calloway (b) (4)	13 Aug 2020 19:26:09
User entered '10 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:24:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:24:38
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Oct 2020 18:25:25
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:25:25
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Oct 2020 18:24:38
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:24:38
User entered '13 Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:24:38
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:05:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with ' ' (Site from DM).	Kim Calloway (b) (4)	15 Oct 2020 03:35:56
DataPoint Un-verified.	Kim Calloway (b) (4)	15 Oct 2020 03:35:52
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4)	15 Oct 2020 03:35:52
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:16:44
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:15:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:15:37
Data point term sent to Coder	System	05 Nov 2020 16:50:44
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:50:43
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 21:21:13
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 Aug 2020 21:21:13
Data point term sent to Coder	System	13 Aug 2020 19:26:07
User entered 'BENZONATE'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:28:12

Audit	User	Time (GMT)
User closed query 'Per DM CLR-REQUERY: Response to previous query is noted. However, please update CM indication term to reconcile with recorded AE term so there is an appropriate match. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:34:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:55:31
Query 'Per DM CLR-REQUERY: Response to previous query is noted. However, please update CM indication term to reconcile with recorded AE term so there is an appropriate match. Please update accordingly. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:50:49
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:50:43
User entered 'Covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:50:43
User opened query 'Per DM CLR-REQUERY: Response to previous query is noted. However, please update CM indication term to reconcile with recorded AE term so there is an appropriate match. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:01:43
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:43:59
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'updated AE is added as Covid per DM and CRA' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:26:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:09:52
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'COUGH'	Kim Calloway (b) (4)	13 Aug 2020 19:25:56
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '200'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:37:13
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with '!' (Site from DM).	Kim Calloway (b) (4)	17 Sep 2020 22:27:54
User entered 'four times daily (QID)' reason for change: Per Query Resolution	(b) (4)	17 Sep 2020 22:27:49
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 15:45:55
User entered 'other (OTHER)'	Kim Calloway (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty; reason for change Data Entry Error	Kim Calloway (b) (4)	17 Sep 2020 22:27:49
User entered 'EVERY 8 HOURS'	Kim Calloway (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '10 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:25:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:25:45
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:25:45
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:25:45
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	28 Oct 2020 14:05:58
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with ' ' (Site from DM). DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:16
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:11
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Oct 2020 10:15:47
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Sep 2020 22:27:49
User entered empty.	System	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:27:49
User entered empty.	System	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:27:49
User entered empty.	System	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
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)	19 Oct 2020 21:57:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:57:30
Data point term sent to Coder	System	19 Oct 2020 13:52:45
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 13:51:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
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)	14 Aug 2020 06:06:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:06:11
Data point term sent to Coder	System	13 Aug 2020 19:28:13
User entered 'ALBUTEROL PRO AIR'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:51:54
User entered 'CHEST CONGESTION/ COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:51:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'CHEST CONGESTION'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
User closed query 'Per CDM re-query: Dose per Administration should be a numerical response only. Please remove the units from this field and update the Dose Unit field as appropriate.' (Site from DM). Query 'Per CDM re-query: Dose per Administration should be a numerical response only. Please remove the units from this field and update the Dose Unit field as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 09:42:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 18:32:16
User entered '32' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:32:08
User opened query 'Per CDM re-query: Dose per Administration should be a numerical response only. Please remove the units from this field and update the Dose Unit field as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:39:17
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:55:31
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:51:13
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:51:07
User entered '32mg' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:51:07
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 18:32:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:32:08
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'puff (PUFF)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'as needed (PRN)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 07 AUG 2020. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 09:42:54
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 07 AUG 2020. ' answered with 'per patient this is correct' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:32:25
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 07 AUG 2020. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:13:56
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query ' Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:44:11
Query ' Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:24:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:23:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:23:59
User opened query ' Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:06:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:06:41
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:52:00
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:10:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:23:59
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:23:59
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	28 Oct 2020 14:06:43
	(b) (4), (b) (6) (b) (4)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with '.' (Site from DM). DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:54
	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:48
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:48
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Oct 2020 10:10:20
	(b) (4), (b) (6) (b) (4)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID, PRODUCTSYNONYM: OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 11:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 11:54:44
Data point term sent to Coder	System	25 Aug 2020 18:07:57
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	25 Aug 2020 18:07:55
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Kim Calloway (b) (4) (b) (4)	25 Aug 2020 18:07:55
User entered 'OMEGA 3 ACID (alpha-linolenic acid, eicosapentaenoic acid, and docosahexaenoic acid)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	25 Aug 2020 18:07:42
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:28:20
Data point term sent to Coder	System	13 Aug 2020 19:30:16
User entered 'OMEGA 3 ACID'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

v6.020 DTW (1102)

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US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'IMMUNE HEALTH'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '1'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'g (g)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:06:48
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' answered with ' ' (Site from DM). DataPoint Un-verified.	Kim Calloway (b) (4)	15 Oct 2020 01:49:15
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4)	15 Oct 2020 01:49:10
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
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)	14 Aug 2020 01:19:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:19:09
Data point term sent to Coder	System	13 Aug 2020 19:32:22
User entered 'VITAMIN C'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'IMMUNE BOOST'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '1'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'tablet (TABLET)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate.' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:45
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:41
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:41
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:17:30
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:33:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:33:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:33:12
Data point term sent to Coder User entered 'MULTIVITAMIN'	System Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:23 13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'SUPPLEMENT'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '1'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'tablet (TABLET)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 14:06:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' answered with ' ' (Site from DM). DataPoint Un-verified.	Kim Calloway (b) (4)	15 Oct 2020 03:37:09
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4)	15 Oct 2020 03:37:05
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:53:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:53:55
Data point term sent to Coder	System	17 Nov 2020 16:37:32
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 06:37:35
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 Sep 2020 06:37:35
Data point term sent to Coder	System	08 Sep 2020 17:54:31
User entered 'Augmentin/Clavulanic acid'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR RQ: Response to previous query noted 'corrected', however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:27:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
Query 'Per DM CLR RQ: Response to previous query noted 'corrected', however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Not an AE see medical history' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:37:05
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User entered 'Worsening of SINUSITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User opened query 'Per DM CLR RQ: Response to previous query noted 'corrected', however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:17:53
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:59:35
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 16:29:55

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:27:16
User entered 'Sinusitis'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '825/125'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:53:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:53:56
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #12. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:41:52
Data point term sent to Coder	System	17 Nov 2020 16:38:33
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 16:37:47
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #12. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:37:21
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #12. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:19:36
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:03:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:03:12
Data point term sent to Coder	System	06 Oct 2020 17:02:11
User entered 'AUGMENTIN/CLAVULANIC ACID'	(b) (4), (b) (6) (b) (4)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:27:39
	(b) (4), (b) (6)	17 Nov 2020 19:09:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Not an AE see medical history' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:38:01
	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User entered 'Worsening of SINUSITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 10:19:31
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Sinusitis'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:44:29
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:27:28
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:27:22
User entered '875/125' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:27:22
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:09:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '875'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '02 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:37:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:37:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:02:10

US3452295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:12

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:51:15
User entered '10 Aug 2020'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:16:50

US3452295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:12

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:51:15
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 19:32:18
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 19:30:07
User entered 'Due to SARS-COV-2 (COVID)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:16:50

US3452295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:12

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:51:15
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	07 Oct 2020 19:32:18
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	07 Oct 2020 19:30:07
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:16:50

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'USA-US208-2020-MRNA-1273-P301000001'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'USA-US208-2020-MRNA-1273-P301000001'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered '19/Aug/2020 09:40'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:12

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)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'USA-US208-2020-MRNA-1273-P301000001'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered '28/Aug/2020 11:40'	System	28 Aug 2020 15:40:06

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:12

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)	07 Oct 2020 17:42:07
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 15:40:06

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'USA-US208-2020-MRNA-1273-P301000001'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:28:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered '09/Sep/2020 22:07'	System	10 Sep 2020 02:07:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:28:12

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)	07 Oct 2020 17:42:07
User entered '1'	(b) (4), (b) (6)	10 Sep 2020 02:07:54