

US3732207 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:13:25

All time stamps listed in this document are displayed in GMT

US3732207

Form: Participant Creation

Generated On: 26 Nov 2020 11:13:25

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 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 11:13:25

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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 11:13:25

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 11:13:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:13:25

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:32 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:32
Height (<i>xxx.x</i>)	178.5 cm
Weight (<i>xxx.x</i>)	211.8 lb
BMI (<i>xxx.x</i>)	30.21529 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 11:13:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 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 11:13:25

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

Generated On: 26 Nov 2020 11:13:25

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 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 11:13:25

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 109418

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

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 11:13:25

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)	27 AUG 2020
Time of assessment (00:00-23:59)	17:32 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:32
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 11:13:25

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)	27 AUG 2020
Time of assessment (00:00-23:59)	18:44 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 18:44
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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)	27 AUG 2020
What was the treatment time? (00:00-23:59)	18:14 (24 HR)
Treatment Date and Time (derived)	27 AUG 2020 18:14
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 11:13:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 AUG 2020

Collection time (00:00-23:59)

17:44 (24 HR)

Collection date and time (derived)

27 AUG 2020 17:44

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:25

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:40	27 AUG 2020 17:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

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 11:13:25

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 27 AUG 2020 18:41

PC Open Date & Time 27 AUG 2020 18:34

PC Close Date & Time 27 AUG 2020 21:04

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 00:04

PC Open Date & Time

27 AUG 2020 21:59

PC Close Date & Time

28 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

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

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):

PC Time Stamp

29 AUG 2020 19:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

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):

PC Time Stamp

30 AUG 2020 13:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

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

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):

PC Time Stamp

31 AUG 2020 19:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

01 SEP 2020 12:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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

27 AUG 2020 18:37

PC Open Date & Time

27 AUG 2020 18:34

PC Close Date & Time

27 AUG 2020 21:04

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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

28 AUG 2020 00:05

PC Open Date & Time

27 AUG 2020 21:59

PC Close Date & Time

28 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

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

29 AUG 2020 19:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

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

30 AUG 2020 13:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

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

31 AUG 2020 19:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

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

01 SEP 2020 12:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

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

02 SEP 2020 12:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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 ☐

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 18:41
PC Open Date & Time	27 AUG 2020 18:34
PC Close Date & Time	27 AUG 2020 21:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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 ☐

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 00:05
PC Open Date & Time	27 AUG 2020 21:59
PC Close Date & Time	28 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

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 ☒

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

Yes ☐	
PC Time stamp	28 AUG 2020 12:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

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 ☒

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

Yes ☐	
PC Time stamp	29 AUG 2020 19:13
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

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 ☒

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

Yes ☐	
PC Time stamp	30 AUG 2020 13:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

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 ☒

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

Yes ☐	
PC Time stamp	31 AUG 2020 19:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

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 ☒

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

Yes ☐	
PC Time stamp	01 SEP 2020 12:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

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 ☒

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

Yes ☐	
PC Time stamp	02 SEP 2020 12:38
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732207

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732207

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732207

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

Timepoint	Pre-Dose ☒
	Post-Dose ☐
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	

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

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	

US3732207

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3732207

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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? _____

US3732207

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:25

Was the sample collected?	Yes ☐
	No ☐

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

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:25

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

US3732207

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:25

Date of Contact	18 SEP 2020
Time of Contact	10:21
Date and Time of Contact (derived)	18 SEP 2020 10:21
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 ☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	70 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	74 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	101.0 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)	78 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

	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	☒

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	82 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	86 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	90 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	94 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	98 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	102 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	106 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	110 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	114 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	118 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	1 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	122 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
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)	126 of 1200	

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

	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	☐

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

Date of Visit	18 SEP 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	18 SEP 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

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

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 _____

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

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

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:13:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:13:25

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 SEP 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:19 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:19
Height (<i>xxx.x</i>)	178.5 cm
Weight (<i>xxx.x</i>)	211.9 lb
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732207

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3732207

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:13:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 SEP 2020

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	SICKD28
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US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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)	

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3732207

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:13:25

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3732207

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:13:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

AEID	USA-US102-2020-MRNA-1273-P30 1000002
Adverse event	SYMPTOMATIC 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)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

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

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:13:25

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

Yes ☒

No ☐

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

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

Name of Medication	AIMAVIG
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINE HEADACHES
Dose per administration	70
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 ☐

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

	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 2008
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	☐

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

Name of Medication	ATIVAN
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
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 ☐

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

	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 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

Name of Medication	ADVIL
Prophylaxis	Yes ☐ No ☒
Indication	SYMPTOMATIC COVID-19
Dose per administration	800
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	EVERY 6 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

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

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	SYMPTOMATIC COVID-19
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

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

US3732207

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:13:25

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:13:25

Date of dosing discontinuation (dd MMM yyyy)

21 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

Date of study discontinuation/completion (dd MMM yyyy) 24 SEP 2020

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

SUBJECT NO LONGER WANTS TO PARTICIPATE DUE TO TOO MANY FOLLOW-UP CALLS/VISITS (SINCE THEY ARE CONFIRMED COVID POSITIVE)

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	☐

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

SAEID	USA-US102-2020-MRNA-1273-P301000002
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:25

SAEID	USA-US102-2020-MRNA-1273-P301000002
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/SEP/2020 12:11
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

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:13:25

SAEID	USA-US102-2020-MRNA-1273-P301000002
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:47
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

US3732207 (Prod: eStudySite - La Mesa - PPDS)

US3732207

Form: Participant Creation

Generated On: 26 Nov 2020 11:13:25

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:57:05
User entered 'US3732207'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:34

US3732207

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:57:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:50:08

US3732207

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:57:18
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:35

US3732207

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:57:18
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:50:08

US3732207

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Sep 2020 00:50:08

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered (b) (6) 1990'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:37

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '30'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '30'	System	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered 'Male (M)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '1'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:13:25

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered '27 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 01:15:29
	(b) (4)	

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:35

US3732207

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:13:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:42
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:13:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:29

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:53:39
Data point term sent to Coder	System	01 Sep 2020 00:52:38
User entered 'migraine headaches'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'un UNK 2008'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '2008'	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 00:53:39
Data point term sent to Coder	System	01 Sep 2020 00:52:38
User entered 'anxiety'	Lauren Arnett (b) (4)	01 Sep 2020 00:51:53
	(b) (4)	

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'un Nov 2010'	Lauren Arnett (b) (4)	01 Sep 2020 00:51:53
	(b) (4)	

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered 'Nov 2010'	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
	(b) (4)	

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '27 Aug 2020'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
	(b) (4)	

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '17:32'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
	(b) (4)	

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 17:32'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '178.5' cm	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
DataPoint set to visible.	(b) (4) System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '211.8' lb	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
DataPoint set to visible.	(b) (4) System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '30.21529'	System	01 Sep 2020 00:54:07
DataPoint set to visible.	System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	01 Sep 2020 00:54:07
DataPoint set to visible.	System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:34
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:17

US3732207

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:34
User entered '27 Aug 2020'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:17
	(b) (4)	

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:40
	(b) (4)	

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '1'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:13:25

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:30
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:55:00

US3732207

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:30
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:55:00

US3732207

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:30
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:55:00

US3732207

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Sep 2020 00:55:00

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:39:29

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered '109418'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:39:29

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:39:29

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:07:14
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4)	09 Sep 2020 21:49:26
User entered 'No (N)'	(b) (4)	
	Lauren Arnett (b) (4)	09 Sep 2020 21:48:58
	(b) (4)	
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:38:28

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated per source ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:56:11
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 17:55:52
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:47:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:22:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:22:42

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:49:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:49:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:49:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:49:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '17:32'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 17:32'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '98.1' F	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '56'	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '16'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '106'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '79'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:13:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:49:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:13:25

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:49:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	01 Sep 2020 00:57:09
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '18:44'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 18:44'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '97.5' F	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '53'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '17'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '126'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '73'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:13:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:10:43
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:14

US3732207

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:10:43
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:14

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered '27 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 01:15:51
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered '18:14'	Lauren Arnett (b) (4)	28 Aug 2020 01:15:51
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 18:14'	System	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered 'ONCE'	System	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:30

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:31
User entered '27 Aug 2020'	Lauren Arnett (b) (4)	01 Sep 2020 00:57:30
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:31
User entered '17:44'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:30

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 17:44'	System	01 Sep 2020 00:57:30

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:25

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 00:57:48
	(b) (4)	

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered '17:40'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 17:40'	System	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:25

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:13:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:52

US3732207

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 00:57:52

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered 'Yes (Y)'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:40:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered '97.5'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:00', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered 'No (N)'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:03', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered '27 Aug 2020 18:41'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 18:34'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 21:04'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:19', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered 'Yes (Y)'	System	28 Aug 2020 07:04:44

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered '97.7'	System	28 Aug 2020 07:04:44

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:30', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered 'No (N)'	System	28 Aug 2020 07:04:44

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered '28 Aug 2020 00:04'	System	28 Aug 2020 07:04:44

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 2'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:19', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered 'Yes (Y)'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:22', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered '97.5'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered 'No (N)'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:27', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 3'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:45', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered 'Yes (Y)'	System	30 Aug 2020 02:12:00

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered '97.7'	System	30 Aug 2020 02:12:00

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:36', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered 'No (N)'	System	30 Aug 2020 02:12:00

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered '29 Aug 2020 19:11'	System	30 Aug 2020 02:12:00

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 4'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:36', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f' User entered 'Yes (Y)'	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f' User entered '97.7'	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f'	System	30 Aug 2020 20:03:51
User entered 'No (N)'	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:48', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f' User entered '30 Aug 2020 13:03'	System	30 Aug 2020 20:03:51
	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 5'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:31', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered 'Yes (Y)'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:34', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered '97.7'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:38', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered 'No (N)'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:40', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered '31 Aug 2020 19:13'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 6'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:31', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered 'Yes (Y)'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:37', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered '97.5'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:38', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered 'No (N)'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc' User entered '01 Sep 2020 12:12'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 7'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:21', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered 'Yes (Y)'	System	02 Sep 2020 19:38:34

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered '97.7'	System	02 Sep 2020 19:38:34

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:30', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered 'No (N)'	System	02 Sep 2020 19:38:34

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:32', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered '02 Sep 2020 12:38'	System	02 Sep 2020 19:38:34

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:24', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a' User entered 'None (1)'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:29', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered 'No (N)'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:32', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered 'No (N)'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:39', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a' User entered 'None (1)'	System	28 Aug 2020 01:37:47
	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:45', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered '27 Aug 2020 18:37'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 18:34'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 21:04'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'None (1)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:54', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'No (N)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'No (N)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'None (1)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:02', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered '28 Aug 2020 00:05'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 2'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:30', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'None (1)'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:32', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'No (N)'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:33', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'No (N)'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:35', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'None (1)'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:36', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 3'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:02', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'None (1)'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:05', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'No (N)'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'No (N)'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'None (1)'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:11', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered '29 Aug 2020 19:12'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 4'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'None (1)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:54', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'No (N)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:55', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'No (N)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'None (1)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered '30 Aug 2020 13:03'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 5'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'None (1)'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:47', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'No (N)'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'No (N)'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'None (1)'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:01', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered '31 Aug 2020 19:14'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 6'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f' User entered 'None (1)'	System	01 Sep 2020 19:12:53
	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:47', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered 'No (N)'	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:48', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered 'No (N)'	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:50', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f' User entered 'None (1)'	System	01 Sep 2020 19:12:53
	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f' User entered '01 Sep 2020 12:12'	System	01 Sep 2020 19:12:53
	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 7'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

[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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:35', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'None (1)'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:42', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'No (N)'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:43', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'No (N)'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'None (1)'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:46', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered '02 Sep 2020 12:38'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:29', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:34', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:37', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:43', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'No (N)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered '27 Aug 2020 18:41'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 18:34'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 21:04'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:10', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:12', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:14', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:16', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:20', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'No (N)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:22', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered '28 Aug 2020 00:05'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 2'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:40', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:42', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:45', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:46', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:49', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'No (N)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 3'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:33', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:31', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'Some interference with activity (2)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:34', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:37', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:39', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:13:01', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'No (N)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:13:04', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered '29 Aug 2020 19:13'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 4'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:04', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:07', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:09', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:10', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:13', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'No (N)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:15', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered '30 Aug 2020 13:04'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 5'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:04', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:10', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:12', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:14', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:16', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'No (N)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:20', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered '31 Aug 2020 19:14'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 6'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:54', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:56', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:58', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:13:01', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:13:03', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'No (N)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:13:05', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered '01 Sep 2020 12:13'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 7'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:49', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:50', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:55', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

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 (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:56', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'No (N)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:58', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered '02 Sep 2020 12:38'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:13:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered 'Yes (Y)'	Linda Vega (b) (4)	03 Sep 2020 22:21:05
	(b) (4)	

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered '03 Sep 2020'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered empty.	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:32
User entered 'Yes (Y)'	Linda Vega (b) (4)	03 Sep 2020 22:21:09
	(b) (4)	

US3732207

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 22:21:09

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered 'Yes (Y)'	Linda Vega (b) (4)	11 Sep 2020 16:32:49
	(b) (4)	

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered '10 Sep 2020'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered empty.	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:10
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:53

US3732207

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:32:53

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered 'Yes (Y)'	Linda Vega (b) (4)	18 Sep 2020 19:23:55
	(b) (4)	

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered '18 Sep 2020'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:13:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered empty.	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:54
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:46

US3732207

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:23:46

US3732207

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:42:13
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:42:03
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:28:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:03:01

US3732207

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:13:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:03:01

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:25

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:25

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered '10:21'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:25

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:21'	System	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:25

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:13:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:31
User entered '19 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:32
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:34
User entered '97'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:38
User entered '99.0' F	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:19:45
User closed query 'Per Source, "Chills = Moderate". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:19:35
Query 'Per Source, "Chills = Moderate". Please re-confirm with Source and Correct.' answered by data change (Site from CRA).	System	10 Nov 2020 03:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:28:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:28:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User opened query 'Per Source, "Chills = Moderate". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 22:24:12
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 22:23:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:23:16
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:19:42
User closed query 'Per Source, "Cough = None". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:19:37
Query 'Per Source, "Cough = None". Please re-confirm with Source and Correct.' answered by data change (Site from CRA).	System	10 Nov 2020 03:28:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:28:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:28:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User opened query 'Per Source, "Cough = None". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 22:25:01
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:42
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:43
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:45
User entered 'Severe (Severe)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:46
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:48
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:50
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:57
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:59
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:01
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:02
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:04
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:09
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:11
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:36
User entered '20 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:37
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:39
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:40
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:42
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:44
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:46
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:47
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:49
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:51
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:53
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:55
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:56
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:59
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:38:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:38:01
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:38:03
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:38:04
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:48:01
User entered '21 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:48:03
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:48:05
User entered '96'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:15:48
User entered '101.0' F	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:16:56
User entered 'Severe (Severe)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:16:58
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:04
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:24
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:33
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:38
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:43
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:45
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:57
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:16
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:19
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:29
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:32
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:20
User entered '22 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:22
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:25
User entered '96'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:28
User entered '99.0' F	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:20:03
User closed query 'Per Source, "Chills = Severe". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:20:01
Query 'Per Source, "Chills = Severe". Please re-confirm with Source and Correct.' answered by data change (Site from CRA).	System	10 Nov 2020 03:29:29
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:29:29
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:29:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User opened query 'Per Source, "Chills = Severe". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 23:23:43
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:30
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:31
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:18
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:21
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:25
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:43
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:44
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:25:03
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:25:07
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:25:09
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:25:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm initial start date of symptoms is the same as teh Contact date (18SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:08:19
Query 'Per CDM: Please confirm initial start date of symptoms is the same as teh Contact date (18SEP2020) or update accordingly' answered with 'Correct as is. Site was unaware of onset of symptoms until called subject for their Day 22 safety call and subject returned same day of staffs awareness of symptoms' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:31:11
User opened query 'Per CDM: Please confirm initial start date of symptoms is the same as teh Contact date (18SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:58:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:28
User entered '18 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:30
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:31
User entered '96'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:33
User entered '97.5' F	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:36
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:37
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:38
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:40
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:41
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:43
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:44
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:46
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:47
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:49
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:50
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:51
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:53
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:56
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:03:27
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:03:11
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '24 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '25 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:15:02
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:14:37

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	15 Oct 2020 00:15:02

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '26 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:15:02

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	15 Oct 2020 00:15:17

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '27 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:15:17

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	15 Oct 2020 00:17:40

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '28 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:40

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	15 Oct 2020 00:17:56

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '29 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:17:56

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:18:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:18:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)'	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '8 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:13:25

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:19:45

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:08:29
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Correct as is. Please previously reported AE of Symptomatic COVID-19' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 03:28:04
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
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	23 Sep 2020 01:20:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:20:24

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

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Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:13:25

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:13:25

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered '20 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:13:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:13:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:38:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:38:19
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:38:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '13:19'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 13:19'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '178.5' cm	(b) (4), (b) (6)	23 Sep 2020 01:22:45
DataPoint set to visible.	System	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '211.9' lb	(b) (4), (b) (6)	23 Sep 2020 01:22:45
DataPoint set to visible.	System	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '97.5' F	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '63'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '18'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '135'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '85'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:23:02

US3732207

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:57
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:23:02

US3732207

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:13:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:42:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:23:10

US3732207

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:42:38
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:23:10

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:43:18
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:43:18
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:43:18
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:13:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:13:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:34:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:33

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:13:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:34:13
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:33

US3732207

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:13:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:34:20
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:45

US3732207

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:13:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:34:20
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:45

US3732207

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:13:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:57:30

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:10:49
User entered 'USA-US102-2020-mRNA-1273-P301000002'	System	23 Sep 2020 16:10:35
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 16:10:35

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Adverse event](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 21:38:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:20
Data point term sent to Coder	System	23 Nov 2020 20:59:25
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:05
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:23:58
' (Site from System).		
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is not the reason for discontinuation. Please reconcile with End of Study/Discontinuation eCRF page and update applicable details accordingly. Otherwise, clarify.'	(b) (4), (b) (6)	23 Oct 2020 23:21:31
canceled (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is not the reason for discontinuation. Please reconcile with End of Study/Discontinuation eCRF page and update applicable details accordingly. Otherwise, clarify.'	(b) (4), (b) (6)	20 Oct 2020 19:45:33
(Site from DM).		
User closed query 'PV Query: Event term is reported as 'Symptomatic COVID-19', however, subject had no symptoms. Please consider updating event term to 'Positive COVID-19 PCR', or provide subject's signs/symptoms associated with COVID-19 infection.'	(b) (4), (b) (6)	08 Oct 2020 13:47:01
(Site from Safety).		

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:46:58
Query 'PV Query: Event term is reported as 'Symptomatic COVID-19', however, subject had no symptoms. Please consider updating event term to 'Positive COVID-19 PCR', or provide subject's signs/symptoms associated with COVID-19 infection.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:04:13
Query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment. ' answered with 'subject decided to withdraw from study.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:03:56
User opened query 'PV Query: Event term is reported as 'Symptomatic COVID-19', however, subject had no symptoms. Please consider updating event term to 'Positive COVID-19 PCR', or provide subject's signs/symptoms associated with COVID-19 infection.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:10:26
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:08:13
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)	22 Sep 2020 23:10:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:10:42
Data point term sent to Coder	System	22 Sep 2020 23:09:38
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '15 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
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	22 Sep 2020 23:09:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 23:09:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:09:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 23:08:39
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	22 Sep 2020 23:08:39
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 23:09:00
User entered '15 Sep 2020 UN:UN' (non-conformant).	System	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:16
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date will not be captured. subject decided to withdraw from study. no further contact will be made' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:13:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:08:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
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 13:29:40
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	22 Sep 2020 23:08:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

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 with 'data entered is correct as is, AE of symptomatic COVID is reason why subject decided to withdraw from study. Site was queried to updated reason for discontinuation to "Due to SARS-CoV-2" in End of Study folder. Please advise if SARS-CoV-2 should have been selected, or if AE was correct the first time' (Site from System).	Lauren Arnett (b) (4)	24 Nov 2020 20:21:08
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	24 Nov 2020 20:14:48
Query 'Per CDM: Dose discontinuation form is has not be completed. Please reconcile. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:31:15
User opened query 'Per CDM: Dose discontinuation form is has not be completed. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:27:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:27:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:26:38
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:26:38
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.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:09:33
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)	30 Oct 2020 10:10:36
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:27:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:26:38
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:26:38
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:22
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'unknown has been selected due to subject withdrawing from participation' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:14:42
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:14:16
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 08:53:39
Query 'Data is required. Please complete.' answered with 'will be updated upon final outcome' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 23:09:35
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 23:08:39
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:32
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:29
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:25
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'confirmed as no ' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:16:26
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:16:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no safety blood work obtained. Just central PCR as positive' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:15:41
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:10:42

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:30
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:13:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 23:08:39

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:13:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:30
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:58:29

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: ERENUMAB, PRODUCTSYNONYM: AIMOVIG [ERENUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:44:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:44:37
Data point term sent to Coder	System	01 Sep 2020 00:59:40
User entered 'aimavig'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'migraine headaches'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '70'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'every month (QM)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'un UNK 2008'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4)	01 Sep 2020 00:59:36
	(b) (4)	

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 01:01:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 01:01:40
Data point term sent to Coder	System	01 Sep 2020 01:00:43
User entered 'ativan'	Lauren Arnett (b) (4)	01 Sep 2020 01:00:37
	(b) (4)	

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'anxiety'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '1'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	01 Sep 2020 01:00:37
	(b) (4)	

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:13:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:13:40
Data point term sent to Coder	System	30 Sep 2020 21:21:55
User entered 'ADVIL'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'SYMPTOMATIC COVID-19'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '800'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'EVERY 6 HOURS'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '15 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[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, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:08:48
	(b) (4), (b) (6)	10 Nov 2020 06:28:30
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:23:49
	(b) (4), (b) (6)	10 Nov 2020 03:23:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:23:44
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 10:09:48
	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 21:23:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 21:23:45
Data point term sent to Coder	System	30 Sep 2020 21:22:56
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:08:51
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.'	(b) (4), (b) (6)	10 Nov 2020 03:26:55
answered with 'updated AE' (Site from DM).		
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:19:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'SYMPTOMATIC COVID-19'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '1000'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'EVERY 6 HOURS'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '17 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[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, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 10:00:30
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 06:28:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:27:31
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:27:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 10:10:10
	(b) (4), (b) (6)	21 Oct 2020 18:10:02
	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:13:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:13:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:15:50

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:13:25

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:16
User entered '21 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:23:02

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:13:25

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:04:56
Query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'updated, please note it was subjects decision to withdraw from study due to positive COVID' (Site from DM).	Lauren Arnett (b) (4)	24 Nov 2020 20:15:41
DataPoint Un-verified.	(b) (4)	
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	24 Nov 2020 20:14:48
User opened query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:48
	(b) (4), (b) (6)	21 Oct 2020 18:14:16
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	24 Sep 2020 21:23:02

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System). DataPoint Un-verified.	System	24 Nov 2020 20:14:57
	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:14:57
User entered empty; reason for change New Information	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:14:57
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System). DataPoint Verified.	System	24 Nov 2020 20:14:48
	(b) (4), (b) (6)	21 Oct 2020 18:14:16
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	24 Sep 2020 21:23:02

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

[Reason for discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

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)	21 Oct 2020 18:14:31
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	24 Sep 2020 21:27:00
User entered 'Subject no longer wants to participate due to too many follow-up calls/visits (since they are confirmed COVID positive)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 21:27:00
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	24 Sep 2020 21:25:04
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:13:25

[Was autopsy performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
User entered '23/Sep/2020 12:11'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:13:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:13:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:13:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
User entered '08/Oct/2020 13:47'	System	08 Oct 2020 13:47:58

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:13:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 13:47:58