

US3562040 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:57:53

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US3562040

Form: Participant Creation

Data signed: (b) (4) 18 Feb 2021 14:42:21

Generated On: 11 Aug 2021 22:57:53

[Participant ID](#)

US3562040

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

US3562040

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 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

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Condition	ATTENTION-DEFICIT/HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Feb 2021 14:42:55

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:51
Height (xxx.x)	64.8 in
Weight (xxx.x)	177 lb
BMI (xxx.x)	29.69841 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 14:42:55

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	14 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

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104100

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Feb 2021 14:42:55

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

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)	14 AUG 2020
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:51
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

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)	14 AUG 2020
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:12
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 14:42:55

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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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 12:39 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:39

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

12:02 (24 HR)

Collection date and time (derived)

14 AUG 2020 12:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	14 AUG 2020 12:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

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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: 11 Aug 2021 22:57:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:13

PC Open Date & Time

14 AUG 2020 12:59

PC Close Date & Time

14 AUG 2020 15:29

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

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

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

PC Time Stamp 14 AUG 2020 19:14

PC Open Date & Time 14 AUG 2020 16:24

PC Close Date & Time 15 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:51

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 19:38

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 23:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

19 AUG 2020 07:58

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 08:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:39

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

14 AUG 2020 13:00

PC Open Date & Time

14 AUG 2020 12:59

PC Close Date & Time

14 AUG 2020 15:29

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 19:15

PC Open Date & Time

14 AUG 2020 16:24

PC Close Date & Time

15 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:52

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 16:36

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 23:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 07:58

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 08:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	20 AUG 2020 12:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 13:00
PC Open Date & Time	14 AUG 2020 12:59
PC Close Date & Time	14 AUG 2020 15:29

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☒
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☒
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☒
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 19:16
PC Open Date & Time	14 AUG 2020 16:24
PC Close Date & Time	15 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	15 AUG 2020 12:56
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	16 AUG 2020 16:36
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	17 AUG 2020 23:59
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1989

EAB) (1725)

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	19 AUG 2020 07:59
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	20 AUG 2020 08:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1989

EAB) (1725)

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	20 AUG 2020 12:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3562040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

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	VISIT2

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:44
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3562040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 SEP 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 11:12

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

US3562040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

09:29 (24 HR)

Collection date and time (derived)

18 SEP 2020 09:29

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:36	18 SEP 2020 09:36
Nasopharyngeal Swab 2	No		

US3562040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 11:47

PC Open Date & Time

18 SEP 2020 11:32

PC Close Date & Time

18 SEP 2020 14:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

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

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

PC Time Stamp 18 SEP 2020 22:41

PC Open Date & Time 18 SEP 2020 14:57

PC Close Date & Time 19 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 09:45

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 23:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 21:26

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 07:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 21:08

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 07:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

18 SEP 2020 11:48

PC Open Date & Time

18 SEP 2020 11:32

PC Close Date & Time

18 SEP 2020 14:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 22:41

PC Open Date & Time

18 SEP 2020 14:57

PC Close Date & Time

19 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 09:45

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 23:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:26

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 07:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 21:08

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 07:01

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 11:48
PC Open Date & Time	18 SEP 2020 11:32
PC Close Date & Time	18 SEP 2020 14:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☒
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☒
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☒
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 22:42
PC Open Date & Time	18 SEP 2020 14:57
PC Close Date & Time	19 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	20 SEP 2020 09:46
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	21 SEP 2020 00:00
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	21 SEP 2020 21:26
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	23 SEP 2020 07:59
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	23 SEP 2020 21:09
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

Yes ☐	
PC Time stamp	25 SEP 2020 07:01
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3562040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	09:11 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:11
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3562040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

09:42 (24 HR)

Collection date and time (derived)

16 OCT 2020 09:42

US3562040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:56

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 10:48:20
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 13:24:03

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 18:51:01

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 12:00:50
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:19:00

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	01 DEC 2020 12:14:37
Patient Cloud Open Date & Time	29 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	122 of 1989

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 00:01:49

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 02:01:13
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 21:37:42

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 13:26:52

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 12:32:31

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3562040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3562040

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562040

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 14:42:55

Generated On: 11 Aug 2021 22:57:53

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

Date of Contact 2 DEC 2020

Time of Contact

Date and Time of Contact (derived)

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 ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	26 NOV 2020

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

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 ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	27 NOV 2020

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

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 ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	30 NOV 2020

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

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 ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	01 DEC 2020

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

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 ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	02 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	98.7 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 ☐

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	03 DEC 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.7 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	☐

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	04 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

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 ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	06 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

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	☐

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	07 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	98.5 F

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

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

Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	09 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	98.5 F

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

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

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	10 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	11 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	14 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.1 F

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

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

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	15 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.1 F

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

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

Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☒
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	12 DEC 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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	13 DEC 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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

	Not Done	☐
Fatigue	None	☐
	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	☐

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 20:16:44

Generated On: 11 Aug 2021 22:57:53

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

Date of Visit 2 DEC 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 2 DEC 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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

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 _____

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

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

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:22

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	4 DEC 2020
Day 5	Yes	6 DEC 2020
Day 7	Yes	8 DEC 2020
Day 9	Yes	09 DEC 2020
Day 14	Yes	15 DEC 2020
Day 21	Yes	22 DEC 2020
Day 28	No	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 DEC 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 14:10
Height (xxx.x)	64.8 in
Weight (xxx.x)	177.3 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 DEC 2020

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

US3562040

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 DEC 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

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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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Feb 2021 14:42:21

Generated On: 11 Aug 2021 22:57:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Feb 2021 14:42:21

Generated On: 11 Aug 2021 22:57:53

AEID	USA-US071-2020-MRNA-1273-P30 1000006
Adverse event	COVID 19 INFECTION
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)	26 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Feb 2021 14:42:21

Generated On: 11 Aug 2021 22:57:53

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ 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	True
Concomitant Medication	False
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication BUPROPION

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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	☒

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication VYVANSE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 50

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
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	☒

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication CLONAZOPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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	☐

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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	☐

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	14 AUG 2020	
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	☒

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INEJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

Name of Medication PFIZER EUA COVID 19 VACCINE

Prophylaxis Yes ☒
No ☐

Indication COVID 19 PROPHYLAXIS

Dose per administration 0.3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 22:18:53

Generated On: 11 Aug 2021 22:57:53

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

US3562040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Feb 2021 14:42:22

Generated On: 11 Aug 2021 22:57:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 08 Apr 2021 22:01:01

Generated On: 11 Aug 2021 22:57:53

Date of study discontinuation/completion (dd MMM yyyy) 04 JAN 2021

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 PT RECEIVED PFIZER VACCINE DURING WEEKEND

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	☐

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

SAEID	USA-US071-2020-MRNA-1273-P301000006
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

SAEID	USA-US071-2020-MRNA-1273-P301000006
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/DEC/2020 16:17
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

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

SAEID	USA-US071-2020-MRNA-1273-P301000006
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/DEC/2020 13:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Feb 2021 14:42:23

Generated On: 11 Aug 2021 22:57:53

SAEID	USA-US071-2020-MRNA-1273-P301000006
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/JAN/2021 08:38
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

US3562040 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562040

Form: Participant Creation

Generated On: 11 Aug 2021 22:57:53

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:31:17
User entered 'US3562040'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:59:33

US3562040

Form: Participant Creation

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:32:10
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:31

US3562040

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	04 Jan 2021 22:45:14
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:32:10
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:59:34

US3562040

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:32:10
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:31

US3562040

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'SCRN'	System	14 Aug 2020 19:44:31

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4)	09 Sep 2020 20:33:57
User entered (b) (6) 1975'	(b) (4), (b) (6)	09 Sep 2020 20:33:57
	RWS_ENDPOINT	14 Aug 2020 18:59:35
	ENDPOINT (b) (4)	

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '45'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'YEARS'	System	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '45'	System	14 Aug 2020 19:44:51

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered 'Male (M)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:33:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:11

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:35:09
User entered '14 Aug 2020'	Dhwani Shah (b) (4)	14 Aug 2020 19:44:51
	(b) (4)	

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'Aug 2020'	System	14 Aug 2020 19:44:51

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '2020'	System	14 Aug 2020 19:44:51

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09
User entered 'Amendment 2 (2)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:51

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:51

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:51

US3562040

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:51

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:51

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4)	09 Sep 2020 20:35:09
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:35:09
	RWS_ENDPOINT	14 Aug 2020 18:59:34
	ENDPOINT (b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'l'	System	14 Aug 2020 19:44:59

US3562040

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:38:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:44:59

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Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:57:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:38:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:48:40

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:35:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:35:09
Data point term sent to Coder	System	17 Aug 2020 14:34:29
User entered 'Depression'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'un UNK 2015'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:09

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'Jan 2015'	System	17 Aug 2020 14:34:09

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '2015'	System	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:34:09

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
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) (b) (4)	17 Aug 2020 14:36:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:36:09
Data point term sent to Coder	System	17 Aug 2020 14:35:31
User entered 'Anxiety'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'un UNK 2015'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:32

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:32

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:34:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:34:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:34:32
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'Jan 2015'	System	17 Aug 2020 14:34:32

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '2015'	System	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:34:32

US3562040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:36:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 14:36:12
Data point term sent to Coder	System	17 Aug 2020 14:35:32
User entered 'Attention-deficit/hyperactivity disorder'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:16

US3562040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'un UNK 2010'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:16

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:16

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:16

US3562040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:16

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:16

US3562040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'Jan 2010'	System	17 Aug 2020 14:35:16

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '2010'	System	17 Aug 2020 14:35:16

US3562040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:35:16

US3562040

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:35:16

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:37:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:37:13
Data point term sent to Coder	System	17 Aug 2020 14:36:33
User entered 'Seasonal allergies'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'un UNK 2000'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'Jan 2000'	System	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '2000'	System	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:35:40

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:37:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:37:13
Data point term sent to Coder	System	17 Aug 2020 14:36:33
User entered 'Gastroesophageal reflux disease'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'un UNK 2017'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'Jan 2017'	System	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '2017'	System	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	17 Aug 2020 14:36:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered '14 Aug 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered '11:51'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '14 Aug 2020 11:51'	System	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered '64.8' in	Dhwani Shah (b) (4)	14 Aug 2020 23:46:02
DataPoint set to visible.	(b) (4) System	14 Aug 2020 19:44:59

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered '177' lb	Dhwani Shah (b) (4)	14 Aug 2020 23:46:02
DataPoint set to visible.	(b) (4) System	14 Aug 2020 19:44:59

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
Amendment Manager: User entered '29.69841'	System	16 Sep 2020 23:57:51
User entered '29.7'	System	14 Aug 2020 23:46:02
DataPoint set to visible.	System	14 Aug 2020 19:44:59

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'kg/m2'	System	14 Aug 2020 23:46:02
DataPoint set to visible.	System	14 Aug 2020 19:44:59

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).		27 Aug 2020 07:44:02
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:47
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 08:46:26
User entered '98.4' F	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:47
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:47
User entered '76'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'bpm'	System	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:47
User entered '16'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'breaths/min'	System	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:47
User entered '110'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Aug 2020 21:55:47
User entered '72'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	14 Aug 2020 23:46:02

US3562040

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49

US3562040

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:44:13
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:45:22

US3562040

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:44:17
User entered '14 Aug 2020'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:22
	(b) (4)	

US3562040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

US3562040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

US3562040

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:46:40
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered '0'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:20
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:46:40

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:48
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:25

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	04 Jan 2021 22:45:14
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:45:48
User entered '14 Aug 2020'	Dhwani Shah (b) (4)	14 Aug 2020 23:38:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:48
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:25

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'VISIT1'	System	14 Aug 2020 23:38:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'The Randomization Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'The Randomization Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 19:04:38

US3562040

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:39:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:39:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 19:04:38
User entered '104100' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 19:04:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 19:04:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:40

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:40

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:45:54
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:23:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '14 Aug 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '11:51'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '14 Aug 2020 11:51'	System	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '98.4' F	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '76'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'bpm'	System	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '16'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'breaths/min'	System	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '110'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '72'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '14 Aug 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		17 Aug 2020 14:20:02
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 23:40:30
User entered '13:12'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '14 Aug 2020 13:12'	System	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '98.9' F	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '80'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'bpm'	System	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '16'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'breaths/min'	System	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '111'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:05
User entered '74'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	14 Aug 2020 23:40:30

US3562040

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:13
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:48

US3562040

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:48

US3562040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:28
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:45:39

US3562040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:28
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:45:39

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Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:28
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:45:39

US3562040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 19:45:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
DataPoint Verified.	System	04 Jan 2021 22:42:37
User entered '14 Aug 2020'	(b) (4), (b) (6)	09 Sep 2020 20:47:28
	Dhwani Shah (b) (4)	14 Aug 2020 19:45:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:28
User entered '12:39'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:45:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '14 Aug 2020 12:39'	System	14 Aug 2020 19:45:39

US3562040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:28
User entered 'Left Arm (LEFT ARM)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 19:45:39

US3562040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:47:28
User entered 'ONCE'	System	14 Aug 2020 19:45:39

US3562040

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 19:45:39

US3562040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:47:59
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:14

US3562040

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	04 Jan 2021 22:45:14
DataPoint Verified.	System	04 Jan 2021 22:42:37
	(b) (4), (b) (6)	09 Sep 2020 20:47:59
User entered '14 Aug 2020'	Dhwani Shah (b) (4)	14 Aug 2020 23:39:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:47:59
User entered '12:02'	Dhwani Shah (b) (4)	14 Aug 2020 23:39:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '14 Aug 2020 12:02'	System	14 Aug 2020 23:39:14

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:50:39
User entered '14 Aug 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

US3562040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

US3562040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:50:39
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:50:39
User entered '12:05'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 23:39:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

US3562040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:38:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Sep 2020 23:25:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Sep 2020 23:25:07
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 23:25:07
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 23:25:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:50:39
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 23:39:28
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

US3562040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:39:28

US3562040

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	14 Aug 2020 23:39:28

US3562040

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:00
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:38:54

US3562040

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'l'	System	14 Aug 2020 23:38:54

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:12:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3e4417a4-b977-4f8d-a3da-4b56adfc1760' User entered 'Yes (Y)'	System	14 Aug 2020 20:13:16
	System	14 Aug 2020 20:13:16

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:13:08', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3e4417a4-b977-4f8d-a3da-4b56adfc1760' User entered '98.9'	System	14 Aug 2020 20:13:16
	System	14 Aug 2020 20:13:16

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:13:13', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3e4417a4-b977-4f8d-a3da-4b56adfc1760'	System	14 Aug 2020 20:13:16
User entered 'No (N)'	System	14 Aug 2020 20:13:16

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:13:15', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3e4417a4-b977-4f8d-a3da-4b56adfc1760' User entered '14 Aug 2020 13:13'	System	14 Aug 2020 20:13:16
	System	14 Aug 2020 20:13:16

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 12:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 15:29'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:13:54', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '39bc6a5d-88d9-4c2e-ab7f-d5983a8ece94' User entered 'Yes (Y)'	System	15 Aug 2020 02:14:39
	System	15 Aug 2020 02:14:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:14:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '39bc6a5d-88d9-4c2e-ab7f-d5983a8ece94' User entered '98.9'	System	15 Aug 2020 02:14:39
	System	15 Aug 2020 02:14:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:14:13', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '39bc6a5d-88d9-4c2e-ab7f-d5983a8ece94'	System	15 Aug 2020 02:14:39
User entered 'Yes (Y)'	System	15 Aug 2020 02:14:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated co med line 6' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 14:44:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Dhwani Shah (b) (4)	21 Aug 2020 20:38:56
Updated with 'updated co med line 6' (Site from System).	(b) (4)	
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Aug 2020 02:14:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:14:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '39bc6a5d-88d9-4c2e-ab7f-d5983a8ece94'	System	15 Aug 2020 02:14:39
User entered '1'	System	15 Aug 2020 02:14:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:14:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '39bc6a5d-88d9-4c2e-ab7f-d5983a8ece94' User entered '0'	System	15 Aug 2020 02:14:39
	System	15 Aug 2020 02:14:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:14:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '39bc6a5d-88d9-4c2e-ab7f-d5983a8ece94' User entered '14 Aug 2020 19:14'	System	15 Aug 2020 02:14:39
	System	15 Aug 2020 02:14:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 16:24'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 2'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:51:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '5896d9fe-0f47-43c3-8034-7c1a68004b73' User entered 'Yes (Y)'	System	15 Aug 2020 19:51:58
	System	15 Aug 2020 19:51:58

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:51:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '5896d9fe-0f47-43c3-8034-7c1a68004b73' User entered '97.8'	System	15 Aug 2020 19:51:58
	System	15 Aug 2020 19:51:58

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:51:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '5896d9fe-0f47-43c3-8034-7c1a68004b73'	System	15 Aug 2020 19:51:58
User entered 'No (N)'	System	15 Aug 2020 19:51:58

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:51:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '5896d9fe-0f47-43c3-8034-7c1a68004b73' User entered '15 Aug 2020 12:51'	System	15 Aug 2020 19:51:58
	System	15 Aug 2020 19:51:58

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 3'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T19:38:38', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e66a9e73-03e3-4857-b621-7662ecf2c875'	System	17 Aug 2020 02:38:56
User entered 'Yes (Y)'	System	17 Aug 2020 02:38:56

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T19:38:43', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e66a9e73-03e3-4857-b621-7662ecf2c875'	System	17 Aug 2020 02:38:56
User entered '98.4'	System	17 Aug 2020 02:38:56

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T19:38:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e66a9e73-03e3-4857-b621-7662ecf2c875'	System	17 Aug 2020 02:38:56
User entered 'No (N)'	System	17 Aug 2020 02:38:56

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T19:38:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e66a9e73-03e3-4857-b621-7662ecf2c875'	System	17 Aug 2020 02:38:56
User entered '16 Aug 2020 19:38'	System	17 Aug 2020 02:38:56

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 4'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:14', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33d73857-491a-41ff-8aa6-b29619c6f96d' User entered 'Yes (Y)'	System	18 Aug 2020 06:59:26
	System	18 Aug 2020 06:59:26

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33d73857-491a-41ff-8aa6-b29619c6f96d' User entered '98.4'	System	18 Aug 2020 06:59:26
	System	18 Aug 2020 06:59:26

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:22', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33d73857-491a-41ff-8aa6-b29619c6f96d'	System	18 Aug 2020 06:59:26
User entered 'No (N)'	System	18 Aug 2020 06:59:26

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:25', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33d73857-491a-41ff-8aa6-b29619c6f96d' User entered '17 Aug 2020 23:59'	System	18 Aug 2020 06:59:26
	System	18 Aug 2020 06:59:26

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 5'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:27', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '35e2e9bc-0cef-4084-a025-0fd added6dee66' User entered 'Yes (Y)'	System	19 Aug 2020 14:58:39
	System	19 Aug 2020 14:58:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:32', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '35e2e9bc-0cef-4084-a025-0fd added6dee66' User entered '97.7'	System	19 Aug 2020 14:58:39
	System	19 Aug 2020 14:58:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:34', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '35e2e9bc-0cef-4084-a025-0fd added6dee66'	System	19 Aug 2020 14:58:39
User entered 'No (N)'	System	19 Aug 2020 14:58:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '35e2e9bc-0cef-4084-a025-0fd added6dee66' User entered '19 Aug 2020 07:58'	System	19 Aug 2020 14:58:39
	System	19 Aug 2020 14:58:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 6'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:24', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f726457c-f5bc-466a-8f8d-2a0ad9a2ead6' User entered 'Yes (Y)'	System	20 Aug 2020 15:35:40
	System	20 Aug 2020 15:35:40

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f726457c-f5bc-466a-8f8d-2a0ad9a2ead6' User entered '98.0'	System	20 Aug 2020 15:35:40
	System	20 Aug 2020 15:35:40

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:34', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f726457c-f5bc-466a-8f8d-2a0ad9a2ead6'	System	20 Aug 2020 15:35:40
User entered 'No (N)'	System	20 Aug 2020 15:35:40

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f726457c-f5bc-466a-8f8d-2a0ad9a2ead6' User entered '20 Aug 2020 08:35'	System	20 Aug 2020 15:35:40
	System	20 Aug 2020 15:35:40

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 7'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:38:54', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'c4bfc2d3-1a4a-4331-9b3c-8785642e9f52' User entered 'Yes (Y)'	System	20 Aug 2020 19:39:08
	System	20 Aug 2020 19:39:08

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'c4bfc2d3-1a4a-4331-9b3c-8785642e9f52' User entered '98.9'	System	20 Aug 2020 19:39:08
	System	20 Aug 2020 19:39:08

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'c4bfc2d3-1a4a-4331-9b3c-8785642e9f52'	System	20 Aug 2020 19:39:08
User entered 'No (N)'	System	20 Aug 2020 19:39:08

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:06', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'c4bfc2d3-1a4a-4331-9b3c-8785642e9f52' User entered '20 Aug 2020 12:39'	System	20 Aug 2020 19:39:08
	System	20 Aug 2020 19:39:08

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T12:59:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2db151c8-eee5-487d-bbf5-7f4a667033ce' User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 20:00:28
	System	14 Aug 2020 20:00:28

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:05', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2db151c8-eee5-487d-bbf5-7f4a667033ce' User entered 'No (N)'	System	14 Aug 2020 20:00:28
	System	14 Aug 2020 20:00:28

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2db151c8-eee5-487d-bbf5-7f4a667033ce' User entered 'No (N)'	System	14 Aug 2020 20:00:28
	System	14 Aug 2020 20:00:28

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:17', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2db151c8-eee5-487d-bbf5-7f4a667033ce' User entered 'None (1)'	System	14 Aug 2020 20:00:28
	System	14 Aug 2020 20:00:28

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2db151c8-eee5-487d-bbf5-7f4a667033ce' User entered '14 Aug 2020 13:00'	System	14 Aug 2020 20:00:28
	System	14 Aug 2020 20:00:28

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 12:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 15:29'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:14:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9d9ae7bb-0546-4316-9c5a-c2288ca0307e'	System	15 Aug 2020 02:15:35
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 02:15:35

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:15:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9d9ae7bb-0546-4316-9c5a-c2288ca0307e' User entered 'No (N)'	System	15 Aug 2020 02:15:35
	System	15 Aug 2020 02:15:35

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:15:11', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9d9ae7bb-0546-4316-9c5a-c2288ca0307e' User entered 'No (N)'	System	15 Aug 2020 02:15:35
	System	15 Aug 2020 02:15:35

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:15:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9d9ae7bb-0546-4316-9c5a-c2288ca0307e' User entered 'None (1)'	System	15 Aug 2020 02:15:35
	System	15 Aug 2020 02:15:35

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:15:33', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9d9ae7bb-0546-4316-9c5a-c2288ca0307e' User entered '14 Aug 2020 19:15'	System	15 Aug 2020 02:15:35
	System	15 Aug 2020 02:15:35

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 16:24'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 2'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:52:18', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '781e282a-f677-45d1-aea7-780538591093'	System	15 Aug 2020 19:52:52
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 19:52:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:52:36', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '781e282a-f677-45d1-aea7-780538591093'	System	15 Aug 2020 19:52:52
User entered 'No (N)'	System	15 Aug 2020 19:52:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:52:40', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '781e282a-f677-45d1-aea7-780538591093' User entered 'No (N)'	System	15 Aug 2020 19:52:52
	System	15 Aug 2020 19:52:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:52:47', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '781e282a-f677-45d1-aea7-780538591093'	System	15 Aug 2020 19:52:52
User entered 'None (1)'	System	15 Aug 2020 19:52:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:52:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '781e282a-f677-45d1-aea7-780538591093' User entered '15 Aug 2020 12:52'	System	15 Aug 2020 19:52:52
	System	15 Aug 2020 19:52:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 3'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:24', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3b11c2bb-4957-4065-90b7-6fa0886280a9' User entered 'None (1)'	System	16 Aug 2020 23:36:40
	System	16 Aug 2020 23:36:40

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3b11c2bb-4957-4065-90b7-6fa0886280a9' User entered 'No (N)'	System	16 Aug 2020 23:36:40
	System	16 Aug 2020 23:36:40

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:27', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3b11c2bb-4957-4065-90b7-6fa0886280a9' User entered 'No (N)'	System	16 Aug 2020 23:36:40
	System	16 Aug 2020 23:36:40

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:35', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3b11c2bb-4957-4065-90b7-6fa0886280a9' User entered 'None (1)'	System	16 Aug 2020 23:36:40
	System	16 Aug 2020 23:36:40

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:38', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '3b11c2bb-4957-4065-90b7-6fa0886280a9' User entered '16 Aug 2020 16:36'	System	16 Aug 2020 23:36:40
	System	16 Aug 2020 23:36:40

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 4'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cd10740b-977c-445c-94b3-5a1592c9e749' User entered 'None (1)'	System	18 Aug 2020 06:59:38
	System	18 Aug 2020 06:59:38

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:30', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cd10740b-977c-445c-94b3-5a1592c9e749' User entered 'No (N)'	System	18 Aug 2020 06:59:38
	System	18 Aug 2020 06:59:38

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:32', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cd10740b-977c-445c-94b3-5a1592c9e749' User entered 'No (N)'	System	18 Aug 2020 06:59:38
	System	18 Aug 2020 06:59:38

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:34', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cd10740b-977c-445c-94b3-5a1592c9e749' User entered 'None (1)'	System	18 Aug 2020 06:59:38
	System	18 Aug 2020 06:59:38

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:36', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cd10740b-977c-445c-94b3-5a1592c9e749' User entered '17 Aug 2020 23:59'	System	18 Aug 2020 06:59:38
	System	18 Aug 2020 06:59:38

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 5'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:40', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '830b1b2f-3a90-4aa9-a2c9-8330f12a10ec'	System	19 Aug 2020 14:58:55
User entered 'None (1)'	System	19 Aug 2020 14:58:55

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '830b1b2f-3a90-4aa9-a2c9-8330f12a10ec'	System	19 Aug 2020 14:58:55
User entered 'No (N)'	System	19 Aug 2020 14:58:55

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:45', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '830b1b2f-3a90-4aa9-a2c9-8330f12a10ec'	System	19 Aug 2020 14:58:55
User entered 'No (N)'	System	19 Aug 2020 14:58:55

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:51', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '830b1b2f-3a90-4aa9-a2c9-8330f12a10ec'	System	19 Aug 2020 14:58:55
User entered 'None (1)'	System	19 Aug 2020 14:58:55

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '830b1b2f-3a90-4aa9-a2c9-8330f12a10ec' User entered '19 Aug 2020 07:58'	System	19 Aug 2020 14:58:55
	System	19 Aug 2020 14:58:55

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 6'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9c0a35fe-1d81-40c8-9c6b-8989f78bfe5c'	System	20 Aug 2020 15:35:52
User entered 'None (1)'	System	20 Aug 2020 15:35:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:43', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9c0a35fe-1d81-40c8-9c6b-8989f78bfe5c'	System	20 Aug 2020 15:35:52
User entered 'No (N)'	System	20 Aug 2020 15:35:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:45', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9c0a35fe-1d81-40c8-9c6b-8989f78bfe5c'	System	20 Aug 2020 15:35:52
User entered 'No (N)'	System	20 Aug 2020 15:35:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:46', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9c0a35fe-1d81-40c8-9c6b-8989f78bfe5c'	System	20 Aug 2020 15:35:52
User entered 'None (1)'	System	20 Aug 2020 15:35:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9c0a35fe-1d81-40c8-9c6b-8989f78bfe5c' User entered '20 Aug 2020 08:35'	System	20 Aug 2020 15:35:52
	System	20 Aug 2020 15:35:52

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 7'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa4b2334-990c-46a2-9076-2d7864caf7df'	System	20 Aug 2020 19:39:20
User entered 'None (1)'	System	20 Aug 2020 19:39:20

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:11', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa4b2334-990c-46a2-9076-2d7864caf7df' User entered 'No (N)'	System	20 Aug 2020 19:39:20
	System	20 Aug 2020 19:39:20

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa4b2334-990c-46a2-9076-2d7864caf7df' User entered 'No (N)'	System	20 Aug 2020 19:39:20
	System	20 Aug 2020 19:39:20

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:16', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa4b2334-990c-46a2-9076-2d7864caf7df'	System	20 Aug 2020 19:39:20
User entered 'None (1)'	System	20 Aug 2020 19:39:20

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:18', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa4b2334-990c-46a2-9076-2d7864caf7df' User entered '20 Aug 2020 12:39'	System	20 Aug 2020 19:39:20
	System	20 Aug 2020 19:39:20

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:35', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'None (0)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'None (0)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:40', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'None (0)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'None (0)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:44', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'None (0)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:47', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'None (0)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered 'No (N)'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T13:00:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e7a627c5-037b-46fa-804d-0ee9d32cafb0' User entered '14 Aug 2020 13:00'	System	14 Aug 2020 20:01:05
	System	14 Aug 2020 20:01:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 12:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 15:29'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109'	System	15 Aug 2020 02:16:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109' User entered 'None (0)'	System	15 Aug 2020 02:16:27
	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109' User entered 'None (0)'	System	15 Aug 2020 02:16:27
	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:10', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109' User entered 'None (0)'	System	15 Aug 2020 02:16:27
	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109' User entered 'None (0)'	System	15 Aug 2020 02:16:27
	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:15', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109' User entered 'None (0)'	System	15 Aug 2020 02:16:27
	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:22', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109'	System	15 Aug 2020 02:16:27
User entered 'No (N)'	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-14T19:16:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '541d89a3-3969-4056-a9ee-9d3f5aecc109'	System	15 Aug 2020 02:16:27
User entered '14 Aug 2020 19:16'	System	15 Aug 2020 02:16:27

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '14 Aug 2020 16:24'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 2'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:53:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583'	System	15 Aug 2020 19:56:28
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:53:08', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583' User entered 'None (0)'	System	15 Aug 2020 19:56:28
	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:53:10', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583' User entered 'None (0)'	System	15 Aug 2020 19:56:28
	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:53:21', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583' User entered 'None (0)'	System	15 Aug 2020 19:56:28
	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:56:13', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583' User entered 'None (0)'	System	15 Aug 2020 19:56:28
	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:56:16', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583' User entered 'None (0)'	System	15 Aug 2020 19:56:28
	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:56:23', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583'	System	15 Aug 2020 19:56:28
User entered 'No (N)'	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-15T12:56:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0daae975-c819-4100-a622-d910c353a583' User entered '15 Aug 2020 12:56'	System	15 Aug 2020 19:56:28
	System	15 Aug 2020 19:56:28

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 3'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:34:47', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d'	System	16 Aug 2020 23:36:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:35:44', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d'	System	16 Aug 2020 23:36:21
User entered 'No interference with activity (1)'	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:35:46', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d' User entered 'No interference with activity (1)'	System	16 Aug 2020 23:36:21
	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d' User entered 'None (0)'	System	16 Aug 2020 23:36:21
	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:10', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d' User entered 'None (0)'	System	16 Aug 2020 23:36:21
	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d' User entered 'None (0)'	System	16 Aug 2020 23:36:21
	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:16', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d' User entered 'No (N)'	System	16 Aug 2020 23:36:21
	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-16T16:36:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '96a32a4d-650a-44ed-a266-2d497019947d' User entered '16 Aug 2020 16:36'	System	16 Aug 2020 23:36:21
	System	16 Aug 2020 23:36:21

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 4'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:39', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered 'None (0)'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered 'None (0)'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered 'None (0)'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:44', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered 'None (0)'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:46', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered 'None (0)'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:47', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered 'None (0)'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74'	System	18 Aug 2020 06:59:56
User entered 'No (N)'	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-17T23:59:51', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9ca6f830-6fe0-4b8c-ab2e-dce69b8fdc74' User entered '17 Aug 2020 23:59'	System	18 Aug 2020 06:59:56
	System	18 Aug 2020 06:59:56

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 5'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:57', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'None (0)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:58:59', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'None (0)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:59:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'None (0)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:59:02', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'None (0)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:59:03', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'None (0)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:59:05', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'None (0)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:59:08', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered 'No (N)'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-19T07:59:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '398cd6e6-0b96-467f-bfc6-bce43430c14f' User entered '19 Aug 2020 07:59'	System	19 Aug 2020 14:59:13
	System	19 Aug 2020 14:59:13

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 6'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:52', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6' User entered 'None (0)'	System	20 Aug 2020 15:36:05
	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6' User entered 'None (0)'	System	20 Aug 2020 15:36:05
	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:55', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6'	System	20 Aug 2020 15:36:05
User entered 'None (0)'	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6' User entered 'None (0)'	System	20 Aug 2020 15:36:05
	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:35:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6'	System	20 Aug 2020 15:36:05
User entered 'None (0)'	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:36:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6'	System	20 Aug 2020 15:36:05
User entered 'None (0)'	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:36:01', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6'	System	20 Aug 2020 15:36:05
User entered 'No (N)'	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T08:36:03', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0c04ffe7-ca21-4a4f-ad19-5ac9d6c6afd6' User entered '20 Aug 2020 08:36'	System	20 Aug 2020 15:36:05
	System	20 Aug 2020 15:36:05

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 7'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:22', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc'	System	20 Aug 2020 19:39:36
User entered 'None (0)'	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:23', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc' User entered 'None (0)'	System	20 Aug 2020 19:39:36
	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:25', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc'	System	20 Aug 2020 19:39:36
User entered 'None (0)'	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc'	System	20 Aug 2020 19:39:36
User entered 'None (0)'	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:27', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc'	System	20 Aug 2020 19:39:36
User entered 'None (0)'	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:29', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc' User entered 'None (0)'	System	20 Aug 2020 19:39:36
	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc'	System	20 Aug 2020 19:39:36
User entered 'No (N)'	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-08-20T12:39:33', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '9f3bf832-4558-46fd-9dc7-f754fe6a75cc' User entered '20 Aug 2020 12:39'	System	20 Aug 2020 19:39:36
	System	20 Aug 2020 19:39:36

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:45:39

US3562040

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:02:53
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:34:42

US3562040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:02:53
User entered '21 Aug 2020'	Dhwani Shah (b) (4)	21 Aug 2020 20:34:42
	(b) (4)	

US3562040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:02:53
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:34:42

US3562040

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:02:53
User entered empty.	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:34:42

US3562040

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:02:58
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:34:51

US3562040

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User entered 'l'	System	21 Aug 2020 20:34:51

US3562040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:11
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	28 Aug 2020 21:15:27

US3562040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:03:11
User entered '28 Aug 2020'	Dhwani Shah (b) (4)	28 Aug 2020 21:15:27
	(b) (4)	

US3562040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:11
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	28 Aug 2020 21:15:27

US3562040

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:11
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Aug 2020 21:15:27

US3562040

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:17
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	28 Aug 2020 21:15:56

US3562040

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:20
User entered 'l'	System	28 Aug 2020 21:15:56

US3562040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:42
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	04 Sep 2020 20:44:34

US3562040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:03:42
User entered '4 Sep 2020'	Dhwani Shah (b) (4)	04 Sep 2020 20:44:34
	(b) (4)	

US3562040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:42
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	04 Sep 2020 20:44:34

US3562040

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:42
User entered empty.	Dhwani Shah (b) (4) (b) (4)	04 Sep 2020 20:44:34

US3562040

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:03:49
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	04 Sep 2020 20:44:41

US3562040

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User entered 'l'	System	04 Sep 2020 20:44:41

US3562040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:38:59
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:50:34

US3562040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:38:59
User entered '18 Sep 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:50:34
	(b) (4)	

US3562040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:38:59
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:50:34

US3562040

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'VISIT2'	System	02 Oct 2020 20:50:34

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '18 Sep 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:52:08
	(b) (4)	

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '09:20'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '18 Sep 2020 09:20'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '98.1' F	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '79'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'bpm'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '16'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'breaths/min'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '107'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '70'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '18 Sep 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:52:08
	(b) (4)	

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '11:44'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '18 Sep 2020 11:44'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '98.0' F	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '62'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'bpm'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '16'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'breaths/min'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '115'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:39:38
User entered '78'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'mmHg'	System	02 Oct 2020 20:52:08

US3562040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:19
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:50:56

US3562040

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:19
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:50:56

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered 'Yes (Y)'		18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered empty.		18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered empty.		18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered '11:12'		18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '18 Sep 2020 11:12'	System	18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered 'Left Arm (LEFT ARM)'		18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:40:50
User entered 'ONCE'	System	18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 18:19:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:41:57
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:38

US3562040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	04 Jan 2021 22:45:14
DataPoint Verified.	System	04 Jan 2021 22:42:37
	(b) (4), (b) (6)	15 Dec 2020 16:41:57
User entered '18 Sep 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:52:38
	(b) (4)	

US3562040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:01:30
User closed query 'Please confirm time response. Per source, 0929 is documented. Please update as applicable. ' (Site from CRA).		16 Dec 2020 22:01:27
Query 'Please confirm time response. Per source, 0929 is documented. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:22:11
User entered '09:29' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:21:47
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 16:41:59
DataPoint Verified.		15 Dec 2020 16:41:57
User opened query 'Please confirm time response. Per source, 0929 is documented. Please update as applicable. ' (Site from CRA).		15 Dec 2020 16:41:54
User entered '12:02'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:38

US3562040

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '18 Sep 2020 09:29'	System	16 Dec 2020 00:21:47
User entered '18 Sep 2020 12:02'	System	02 Oct 2020 20:52:38

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:42:21
User entered '18 Sep 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:52:55
	(b) (4)	

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:42:28
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:01:13
User closed query 'Please confirm time response. Per source, swab was collected at 0936. Please update as applicable. ' (Site from CRA).		16 Dec 2020 22:01:10
Query 'Please confirm time response. Per source, swab was collected at 0936. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:21:12
User entered '09:36' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:20:56
User opened query 'Please confirm time response. Per source, swab was collected at 0936. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 16:42:54
User entered '12:05'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered '18 Sep 2020 09:36'	System	16 Dec 2020 00:20:56
User entered '18 Sep 2020 12:05'	System	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:43:04
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:43:07
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered empty.	System	02 Oct 2020 20:52:55

US3562040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:43:15
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:51:02

US3562040

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:49
User entered 'l'	System	02 Oct 2020 20:51:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '43106cb1-784e-421c-903d-f246c529d3af' User entered 'Yes (Y)'	System	18 Sep 2020 18:47:33
	System	18 Sep 2020 18:47:33

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:16', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '43106cb1-784e-421c-903d-f246c529d3af' User entered '98.0'	System	18 Sep 2020 18:47:33
	System	18 Sep 2020 18:47:33

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:20', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '43106cb1-784e-421c-903d-f246c529d3af' User entered 'No (N)'	System	18 Sep 2020 18:47:33
	System	18 Sep 2020 18:47:33

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '43106cb1-784e-421c-903d-f246c529d3af' User entered '18 Sep 2020 11:47'	System	18 Sep 2020 18:47:33
	System	18 Sep 2020 18:47:33

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 11:32'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:40:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a37e69d4-a61b-4c4a-927d-e29b53127509' User entered 'Yes (Y)'	System	19 Sep 2020 05:41:05
	System	19 Sep 2020 05:41:05

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:40:48', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a37e69d4-a61b-4c4a-927d-e29b53127509' User entered '98.0'	System	19 Sep 2020 05:41:05
	System	19 Sep 2020 05:41:05

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:40:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a37e69d4-a61b-4c4a-927d-e29b53127509' User entered 'Yes (Y)'	System	19 Sep 2020 05:41:05
	System	19 Sep 2020 05:41:05

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SW pt and added con med line 6' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 05:35:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Dhwani Shah (b) (4)	25 Sep 2020 23:11:24
and added con med line 6' (Site from System).	(b) (4)	
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Sep 2020 05:41:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:40:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a37e69d4-a61b-4c4a-927d-e29b53127509'	System	19 Sep 2020 05:41:05
User entered '1'	System	19 Sep 2020 05:41:05

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:40:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a37e69d4-a61b-4c4a-927d-e29b53127509' User entered '0'	System	19 Sep 2020 05:41:05
	System	19 Sep 2020 05:41:05

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:02', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a37e69d4-a61b-4c4a-927d-e29b53127509' User entered '18 Sep 2020 22:41'	System	19 Sep 2020 05:41:05
	System	19 Sep 2020 05:41:05

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 14:57'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 2'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:11', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e1e9bfa6-cc3a-4034-a4e4-6c7f31c31d6d' User entered 'Yes (Y)'	System	20 Sep 2020 16:45:31
	System	20 Sep 2020 16:45:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:23', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e1e9bfa6-cc3a-4034-a4e4-6c7f31c31d6d' User entered '98.2'	System	20 Sep 2020 16:45:31
	System	20 Sep 2020 16:45:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:01', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e1e9bfa6-cc3a-4034-a4e4-6c7f31c31d6d'	System	20 Sep 2020 16:45:31
User entered 'No (N)'	System	20 Sep 2020 16:45:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:29', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'e1e9bfa6-cc3a-4034-a4e4-6c7f31c31d6d' User entered '20 Sep 2020 09:45'	System	20 Sep 2020 16:45:31
	System	20 Sep 2020 16:45:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 3'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:14', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a9c34247-37f2-4096-95cf-99f7193ab783' User entered 'Yes (Y)'	System	21 Sep 2020 06:59:31
	System	21 Sep 2020 06:59:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:22', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a9c34247-37f2-4096-95cf-99f7193ab783' User entered '97.3'	System	21 Sep 2020 06:59:31
	System	21 Sep 2020 06:59:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a9c34247-37f2-4096-95cf-99f7193ab783'	System	21 Sep 2020 06:59:31
User entered 'No (N)'	System	21 Sep 2020 06:59:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a9c34247-37f2-4096-95cf-99f7193ab783' User entered '20 Sep 2020 23:59'	System	21 Sep 2020 06:59:31
	System	21 Sep 2020 06:59:31

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 4'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '21d7391a-ed7f-454f-bf6d-a41121d413ca' User entered 'Yes (Y)'	System	22 Sep 2020 04:26:19
	System	22 Sep 2020 04:26:19

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '21d7391a-ed7f-454f-bf6d-a41121d413ca' User entered '97.8'	System	22 Sep 2020 04:26:19
	System	22 Sep 2020 04:26:19

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '21d7391a-ed7f-454f-bf6d-a41121d413ca'	System	22 Sep 2020 04:26:19
User entered 'No (N)'	System	22 Sep 2020 04:26:19

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:15', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '21d7391a-ed7f-454f-bf6d-a41121d413ca' User entered '21 Sep 2020 21:26'	System	22 Sep 2020 04:26:19
	System	22 Sep 2020 04:26:19

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 5'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:58:52', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '74cbe8f3-2b0f-4de7-b27f-e1761d48a02e' User entered 'Yes (Y)'	System	23 Sep 2020 14:59:04
	System	23 Sep 2020 14:59:04

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:58:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '74cbe8f3-2b0f-4de7-b27f-e1761d48a02e' User entered '98.1'	System	23 Sep 2020 14:59:04
	System	23 Sep 2020 14:59:04

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:58:59', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '74cbe8f3-2b0f-4de7-b27f-e1761d48a02e' User entered 'No (N)'	System	23 Sep 2020 14:59:04
	System	23 Sep 2020 14:59:04

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:01', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '74cbe8f3-2b0f-4de7-b27f-e1761d48a02e' User entered '23 Sep 2020 07:59'	System	23 Sep 2020 14:59:04
	System	23 Sep 2020 14:59:04

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 6'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:32', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2769f541-acb5-4545-a6e2-ebe7c7eeda0f' User entered 'Yes (Y)'	System	24 Sep 2020 04:08:48
	System	24 Sep 2020 04:08:48

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:38', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2769f541-acb5-4545-a6e2-ebe7c7eeda0f' User entered '98.1'	System	24 Sep 2020 04:08:48
	System	24 Sep 2020 04:08:48

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2769f541-acb5-4545-a6e2-ebe7c7eeda0f' User entered 'No (N)'	System	24 Sep 2020 04:08:48
	System	24 Sep 2020 04:08:48

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:43', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '2769f541-acb5-4545-a6e2-ebe7c7eeda0f' User entered '23 Sep 2020 21:08'	System	24 Sep 2020 04:08:48
	System	24 Sep 2020 04:08:48

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 7'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:00:14', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f029aced-20a4-4116-83a9-19e3f845a795' User entered 'Yes (Y)'	System	25 Sep 2020 14:00:30
	System	25 Sep 2020 14:00:30

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:00:20', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f029aced-20a4-4116-83a9-19e3f845a795' User entered '98.1'	System	25 Sep 2020 14:00:30
	System	25 Sep 2020 14:00:30

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:00:23', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f029aced-20a4-4116-83a9-19e3f845a795'	System	25 Sep 2020 14:00:30
User entered 'No (N)'	System	25 Sep 2020 14:00:30

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:00:27', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f029aced-20a4-4116-83a9-19e3f845a795' User entered '25 Sep 2020 07:00'	System	25 Sep 2020 14:00:30
	System	25 Sep 2020 14:00:30

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:35', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f4d8c106-4245-4402-9712-ffa8a8fc3e23'	System	18 Sep 2020 18:48:04
User entered 'None (1)'	System	18 Sep 2020 18:48:04

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:48', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f4d8c106-4245-4402-9712-ffa8a8fc3e23'	System	18 Sep 2020 18:48:04
User entered 'No (N)'	System	18 Sep 2020 18:48:04

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f4d8c106-4245-4402-9712-ffa8a8fc3e23' User entered 'No (N)'	System	18 Sep 2020 18:48:04
	System	18 Sep 2020 18:48:04

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:47:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f4d8c106-4245-4402-9712-ffa8a8fc3e23'	System	18 Sep 2020 18:48:04
User entered 'None (1)'	System	18 Sep 2020 18:48:04

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'f4d8c106-4245-4402-9712-ffa8a8fc3e23' User entered '18 Sep 2020 11:48'	System	18 Sep 2020 18:48:04
	System	18 Sep 2020 18:48:04

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 11:32'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa2c8d29-d4d9-4749-8b33-fed1f57414b8'	System	19 Sep 2020 05:41:30
User entered 'None (1)'	System	19 Sep 2020 05:41:30

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:11', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa2c8d29-d4d9-4749-8b33-fed1f57414b8' User entered 'No (N)'	System	19 Sep 2020 05:41:30
	System	19 Sep 2020 05:41:30

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:18', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa2c8d29-d4d9-4749-8b33-fed1f57414b8' User entered 'No (N)'	System	19 Sep 2020 05:41:30
	System	19 Sep 2020 05:41:30

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:21', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa2c8d29-d4d9-4749-8b33-fed1f57414b8'	System	19 Sep 2020 05:41:30
User entered 'None (1)'	System	19 Sep 2020 05:41:30

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:27', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa2c8d29-d4d9-4749-8b33-fed1f57414b8' User entered '18 Sep 2020 22:41'	System	19 Sep 2020 05:41:30
	System	19 Sep 2020 05:41:30

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 14:57'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 2'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:35', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8967e73e-f69f-4f47-a3cf-1a9311bd5c16' User entered 'None (1)'	System	20 Sep 2020 16:45:48
	System	20 Sep 2020 16:45:48

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:38', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8967e73e-f69f-4f47-a3cf-1a9311bd5c16' User entered 'No (N)'	System	20 Sep 2020 16:45:48
	System	20 Sep 2020 16:45:48

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8967e73e-f69f-4f47-a3cf-1a9311bd5c16' User entered 'No (N)'	System	20 Sep 2020 16:45:48
	System	20 Sep 2020 16:45:48

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:43', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8967e73e-f69f-4f47-a3cf-1a9311bd5c16'	System	20 Sep 2020 16:45:48
User entered 'None (1)'	System	20 Sep 2020 16:45:48

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:45', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8967e73e-f69f-4f47-a3cf-1a9311bd5c16' User entered '20 Sep 2020 09:45'	System	20 Sep 2020 16:45:48
	System	20 Sep 2020 16:45:48

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 3'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:32', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cccbd0fe-d3c4-4c02-b10d-2c7ed9dbc6c6' User entered 'None (1)'	System	21 Sep 2020 06:59:47
	System	21 Sep 2020 06:59:47

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:38', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cccabd0fe-d3c4-4c02-b10d-2c7ed9dbc6c6' User entered 'No (N)'	System	21 Sep 2020 06:59:47
	System	21 Sep 2020 06:59:47

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:40', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cccabd0fe-d3c4-4c02-b10d-2c7ed9dbc6c6' User entered 'No (N)'	System	21 Sep 2020 06:59:47
	System	21 Sep 2020 06:59:47

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cccbd0fe-d3c4-4c02-b10d-2c7ed9dbc6c6' User entered 'None (1)'	System	21 Sep 2020 06:59:47
	System	21 Sep 2020 06:59:47

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:45', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'cccabd0fe-d3c4-4c02-b10d-2c7ed9dbc6c6' User entered '20 Sep 2020 23:59'	System	21 Sep 2020 06:59:47
	System	21 Sep 2020 06:59:47

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 4'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:18', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33168967-cca1-40bd-a718-3da8ad7797a0' User entered 'None (1)'	System	22 Sep 2020 04:26:26
	System	22 Sep 2020 04:26:26

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:20', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33168967-cca1-40bd-a718-3da8ad7797a0' User entered 'No (N)'	System	22 Sep 2020 04:26:26
	System	22 Sep 2020 04:26:26

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:21', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33168967-cca1-40bd-a718-3da8ad7797a0' User entered 'No (N)'	System	22 Sep 2020 04:26:26
	System	22 Sep 2020 04:26:26

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:23', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33168967-cca1-40bd-a718-3da8ad7797a0' User entered 'None (1)'	System	22 Sep 2020 04:26:26
	System	22 Sep 2020 04:26:26

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:25', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '33168967-cca1-40bd-a718-3da8ad7797a0' User entered '21 Sep 2020 21:26'	System	22 Sep 2020 04:26:26
	System	22 Sep 2020 04:26:26

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 5'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:06', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '129f368c-3ecf-4ca5-a87d-c9e97162ee13'	System	23 Sep 2020 14:59:14
User entered 'None (1)'	System	23 Sep 2020 14:59:14

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '129f368c-3ecf-4ca5-a87d-c9e97162ee13'	System	23 Sep 2020 14:59:14
User entered 'No (N)'	System	23 Sep 2020 14:59:14

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '129f368c-3ecf-4ca5-a87d-c9e97162ee13' User entered 'No (N)'	System	23 Sep 2020 14:59:14
	System	23 Sep 2020 14:59:14

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:10', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '129f368c-3ecf-4ca5-a87d-c9e97162ee13'	System	23 Sep 2020 14:59:14
User entered 'None (1)'	System	23 Sep 2020 14:59:14

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '129f368c-3ecf-4ca5-a87d-c9e97162ee13' User entered '23 Sep 2020 07:59'	System	23 Sep 2020 14:59:14
	System	23 Sep 2020 14:59:14

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 6'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:46', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd72527c0-3285-48a3-be38-f9d2d4b3f827' User entered 'None (1)'	System	24 Sep 2020 04:08:54
	System	24 Sep 2020 04:08:54

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:48', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd72527c0-3285-48a3-be38-f9d2d4b3f827' User entered 'No (N)'	System	24 Sep 2020 04:08:54
	System	24 Sep 2020 04:08:54

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd72527c0-3285-48a3-be38-f9d2d4b3f827' User entered 'No (N)'	System	24 Sep 2020 04:08:54
	System	24 Sep 2020 04:08:54

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd72527c0-3285-48a3-be38-f9d2d4b3f827' User entered 'None (1)'	System	24 Sep 2020 04:08:54
	System	24 Sep 2020 04:08:54

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:52', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd72527c0-3285-48a3-be38-f9d2d4b3f827' User entered '23 Sep 2020 21:08'	System	24 Sep 2020 04:08:54
	System	24 Sep 2020 04:08:54

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 7'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '62be7977-6263-4030-b6fb-edac77ecef88'	System	25 Sep 2020 14:01:39
User entered 'None (1)'	System	25 Sep 2020 14:01:39

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '62be7977-6263-4030-b6fb-edac77ecef88'	System	25 Sep 2020 14:01:39
User entered 'No (N)'	System	25 Sep 2020 14:01:39

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:32', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '62be7977-6263-4030-b6fb-edac77ecef88'	System	25 Sep 2020 14:01:39
User entered 'No (N)'	System	25 Sep 2020 14:01:39

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:33', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '62be7977-6263-4030-b6fb-edac77ecef88'	System	25 Sep 2020 14:01:39
User entered 'None (1)'	System	25 Sep 2020 14:01:39

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:36', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '62be7977-6263-4030-b6fb-edac77ecef88' User entered '25 Sep 2020 07:01'	System	25 Sep 2020 14:01:39
	System	25 Sep 2020 14:01:39

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered 'None (0)'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:05', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered 'None (0)'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered 'None (0)'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered 'None (0)'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:11', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered 'None (0)'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:12', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered 'None (0)'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:18', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa'	System	18 Sep 2020 18:48:23
User entered 'No (N)'	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T11:48:21', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8cb31091-ccb3-47dc-a260-b7119943f3aa' User entered '18 Sep 2020 11:48'	System	18 Sep 2020 18:48:23
	System	18 Sep 2020 18:48:23

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 11:32'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:47', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa'	System	19 Sep 2020 05:42:17
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa' User entered 'None (0)'	System	19 Sep 2020 05:42:17
	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa' User entered 'None (0)'	System	19 Sep 2020 05:42:17
	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:41:55', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa' User entered 'None (0)'	System	19 Sep 2020 05:42:17
	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:42:02', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa'	System	19 Sep 2020 05:42:17
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:42:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa' User entered 'None (0)'	System	19 Sep 2020 05:42:17
	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:42:09', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa'	System	19 Sep 2020 05:42:17
User entered 'No (N)'	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-18T22:42:15', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a5bb3ef3-8f55-407f-bc74-dcf22fea02aa' User entered '18 Sep 2020 22:42'	System	19 Sep 2020 05:42:17
	System	19 Sep 2020 05:42:17

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '18 Sep 2020 14:57'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 2'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered 'None (0)'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:51', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered 'None (0)'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered 'None (0)'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:54', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered 'None (0)'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered 'None (0)'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:45:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered 'None (0)'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:46:01', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4'	System	20 Sep 2020 16:46:04
User entered 'No (N)'	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T09:46:03', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '465b0bef-95e3-495d-8d31-01bf930b0ff4' User entered '20 Sep 2020 09:46'	System	20 Sep 2020 16:46:04
	System	20 Sep 2020 16:46:04

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 3'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'None (0)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:52', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'None (0)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:54', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'None (0)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:55', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'None (0)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:57', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'None (0)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-20T23:59:59', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'None (0)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T00:00:01', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered 'No (N)'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T00:00:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'a277f82a-302d-4596-b57c-e2c7cd15a6df' User entered '21 Sep 2020 00:00'	System	21 Sep 2020 07:00:06
	System	21 Sep 2020 07:00:06

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 4'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8' User entered 'None (0)'	System	22 Sep 2020 04:26:42
	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:30', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8' User entered 'None (0)'	System	22 Sep 2020 04:26:42
	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8' User entered 'None (0)'	System	22 Sep 2020 04:26:42
	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:33', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8' User entered 'None (0)'	System	22 Sep 2020 04:26:42
	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:34', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8' User entered 'None (0)'	System	22 Sep 2020 04:26:42
	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:36', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8' User entered 'None (0)'	System	22 Sep 2020 04:26:42
	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8'	System	22 Sep 2020 04:26:42
User entered 'No (N)'	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-21T21:26:40', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '4118c743-8a46-4cd6-81ac-fd02b84a44f8'	System	22 Sep 2020 04:26:42
User entered '21 Sep 2020 21:26'	System	22 Sep 2020 04:26:42

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 5'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:15', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'None (0)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:16', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'None (0)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:17', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'None (0)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'None (0)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:21', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'None (0)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:22', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'None (0)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:24', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered 'No (N)'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T07:59:26', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1080b2c7-729f-4154-9b64-ed4ce8b54265' User entered '23 Sep 2020 07:59'	System	23 Sep 2020 14:59:29
	System	23 Sep 2020 14:59:29

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 6'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:55', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'None (0)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'None (0)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:58', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'None (0)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:08:59', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'None (0)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:09:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'None (0)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:09:02', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'None (0)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:09:05', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered 'No (N)'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-23T21:09:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'ee3e94c4-c410-4951-8931-3561a90c9526' User entered '23 Sep 2020 21:09'	System	24 Sep 2020 04:09:09
	System	24 Sep 2020 04:09:09

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	18 Sep 2020 18:19:02
User entered 'Day 7'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:39', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2' User entered 'None (0)'	System	25 Sep 2020 14:01:52
	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2' User entered 'None (0)'	System	25 Sep 2020 14:01:52
	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2' User entered 'None (0)'	System	25 Sep 2020 14:01:52
	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:44', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2' User entered 'None (0)'	System	25 Sep 2020 14:01:52
	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:45', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2' User entered 'None (0)'	System	25 Sep 2020 14:01:52
	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:46', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2' User entered 'None (0)'	System	25 Sep 2020 14:01:52
	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:48', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2'	System	25 Sep 2020 14:01:52
User entered 'No (N)'	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-09-25T07:01:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '93596bf5-dfd0-47c6-a827-5d45387fd8d2'	System	25 Sep 2020 14:01:52
User entered '25 Sep 2020 07:01'	System	25 Sep 2020 14:01:52

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:19:02

US3562040

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:19:02

US3562040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:29
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:44:48
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:17

US3562040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:29
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:44:48
User entered '25 Sep 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:53:17
	(b) (4)	

US3562040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:29
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:44:48
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:17

US3562040

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:29
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:44:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:17

US3562040

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:29
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:44:55
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:23

US3562040

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:29
User entered 'l'	System	02 Oct 2020 20:53:23

US3562040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:45
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:54
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:36

US3562040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:45
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:21:08
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 07:59:18
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONFIRMED AS IT IS' (Site from System).	Dhwani Shah (b) (4)	16 Dec 2020 00:10:41
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	16 Dec 2020 00:10:08
User entered '01 Oct 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Dec 2020 00:10:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:46:54
User entered '2 Oct 2020'	Dhwani Shah (b) (4)	02 Oct 2020 20:53:36
	(b) (4)	

US3562040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:45
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:54
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:36

US3562040

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:45
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:54
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:36

US3562040

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:45
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:47:01
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 20:53:42

US3562040

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:45
User entered 'l'	System	02 Oct 2020 20:53:42

US3562040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:47:19
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	17 Oct 2020 00:02:32

US3562040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:47:19
User entered '9 Oct 2020'	Dhwani Shah (b) (4)	17 Oct 2020 00:02:32
	(b) (4)	

US3562040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:47:19
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	17 Oct 2020 00:02:32

US3562040

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:47:19
User entered empty.	Dhwani Shah (b) (4)	17 Oct 2020 00:02:32

US3562040

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:47:26
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	17 Oct 2020 00:02:37

US3562040

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:38:26
User entered 'l'	System	17 Oct 2020 00:02:37

US3562040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:22
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:16

US3562040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	04 Jan 2021 22:45:14
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:48:22
User entered '16 Oct 2020'	Dhwani Shah (b) (4)	17 Oct 2020 00:03:16
	(b) (4)	

US3562040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:22
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:16

US3562040

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered 'VISIT3'	System	17 Oct 2020 00:03:16

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '16 Oct 2020'	Dhwani Shah (b) (4)	17 Oct 2020 00:03:51
	(b) (4)	

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '09:11'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered '16 Oct 2020 09:11'	System	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '97.7' F	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '69'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered 'bpm'	System	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '16'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered 'breaths/min'	System	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '115'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered 'mmHg'	System	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:46
User entered '72'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered 'mmHg'	System	17 Oct 2020 00:03:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07

US3562040

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07

US3562040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:55
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:04:25

US3562040

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:48:55
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:04:25

US3562040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:21
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:04:45

US3562040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	04 Jan 2021 22:45:14
DataPoint Verified.	System	04 Jan 2021 22:42:37
	(b) (4), (b) (6)	15 Dec 2020 16:49:21
User entered '16 Oct 2020'	Dhwani Shah (b) (4)	17 Oct 2020 00:04:45
	(b) (4)	

US3562040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:21
User entered '09:42'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:04:45

US3562040

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered '16 Oct 2020 09:42'	System	17 Oct 2020 00:04:45

US3562040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:28
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:04:51

US3562040

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:49:07
User entered 'I'	System	17 Oct 2020 00:04:51

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 64'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-15T10:47:53', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8e9f8fec-417f-42ff-b750-036fc18d6fd2'	System	15 Oct 2020 17:48:23
User entered 'No (N)'	System	15 Oct 2020 17:48:23

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-15T10:48:14', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8e9f8fec-417f-42ff-b750-036fc18d6fd2'	System	15 Oct 2020 17:48:23
User entered 'No (N)'	System	15 Oct 2020 17:48:23

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-15T10:48:20', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '8e9f8fec-417f-42ff-b750-036fc18d6fd2' User entered '15 Oct 2020 10:48:20'	System	15 Oct 2020 17:48:23
	System	15 Oct 2020 17:48:23

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 71'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-23T13:23:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '24e5aa30-b0ef-4d96-a9d0-fb6db98684b7'	System	23 Oct 2020 20:24:05
User entered 'No (N)'	System	23 Oct 2020 20:24:05

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-23T13:23:41', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '24e5aa30-b0ef-4d96-a9d0-fb6db98684b7'	System	23 Oct 2020 20:24:05
User entered 'No (N)'	System	23 Oct 2020 20:24:05

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-23T13:24:03', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '24e5aa30-b0ef-4d96-a9d0-fb6db98684b7' User entered '23 Oct 2020 13:24:03'	System	23 Oct 2020 20:24:05
	System	23 Oct 2020 20:24:05

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 78'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-28T18:50:43', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '667b2a8c-13b8-450e-a9c5-0bcf0fd2881c'	System	29 Oct 2020 01:51:04
User entered 'No (N)'	System	29 Oct 2020 01:51:04

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-28T18:50:57', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '667b2a8c-13b8-450e-a9c5-0bcf0fd2881c' User entered 'No (N)'	System	29 Oct 2020 01:51:04
	System	29 Oct 2020 01:51:04

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-10-28T18:51:01', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '667b2a8c-13b8-450e-a9c5-0bcf0fd2881c' User entered '28 Oct 2020 18:51:01'	System	29 Oct 2020 01:51:04
	System	29 Oct 2020 01:51:04

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 92'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-13T12:00:23', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd6905e91-856c-428c-993c-d51b2ff52987'	System	13 Nov 2020 19:00:58
User entered 'No (N)'	System	13 Nov 2020 19:00:58

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-13T12:00:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd6905e91-856c-428c-993c-d51b2ff52987'	System	13 Nov 2020 19:00:58
User entered 'Yes (Y)'	System	13 Nov 2020 19:00:58

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-13T12:00:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd6905e91-856c-428c-993c-d51b2ff52987'	System	13 Nov 2020 19:00:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 19:00:58

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-13T12:00:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'd6905e91-856c-428c-993c-d51b2ff52987' User entered '13 Nov 2020 12:00:50'	System	13 Nov 2020 19:00:58
	System	13 Nov 2020 19:00:58

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered 'Day 99'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-18T00:18:50', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'b452713a-65fc-4663-8c13-bcba8e359626' User entered 'No (N)'	System	18 Nov 2020 07:19:03
	System	18 Nov 2020 07:19:03

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-18T00:18:56', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'b452713a-65fc-4663-8c13-bcba8e359626' User entered 'No (N)'	System	18 Nov 2020 07:19:03
	System	18 Nov 2020 07:19:03

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-11-18T00:19:00', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'b452713a-65fc-4663-8c13-bcba8e359626' User entered '18 Nov 2020 00:19:00'	System	18 Nov 2020 07:19:03
	System	18 Nov 2020 07:19:03

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 19:45:39

US3562040

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:01:52
Data entry locked.	System	14 Aug 2020 19:45:39
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 19:45:39

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Activated.	System	04 Jan 2021 22:45:14
DataPoint Inactivated.	System	04 Jan 2021 22:42:37
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:13:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'Yes (Y)'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:13:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080'	System	01 Dec 2020 19:14:50
User entered 'Yes (Y)'	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:13:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080'	System	01 Dec 2020 19:14:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:13:43', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080'	System	01 Dec 2020 19:14:50
User entered 'Yes (Y)'	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'l'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'I'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'l'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'l'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'I'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'l'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'l'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'l'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:07', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '0'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:19', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080'	System	01 Dec 2020 19:14:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered 'No (N)'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-01T12:14:37', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: 'aa3bb521-6b60-40b9-afde-97f24e43e080' User entered '01 Dec 2020 12:14:37'	System	01 Dec 2020 19:14:50
	System	01 Dec 2020 19:14:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-06T00:01:36', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '612ca3a9-0c77-4d06-98b6-53e55db0a02a' User entered 'No (N)'	System	06 Dec 2020 07:01:50
	System	06 Dec 2020 07:01:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-06T00:01:46', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '612ca3a9-0c77-4d06-98b6-53e55db0a02a' User entered 'No (N)'	System	06 Dec 2020 07:01:50
	System	06 Dec 2020 07:01:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-06T00:01:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '612ca3a9-0c77-4d06-98b6-53e55db0a02a' User entered '06 Dec 2020 00:01:49'	System	06 Dec 2020 07:01:50
	System	06 Dec 2020 07:01:50

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-13T02:00:59', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '7183ee3f-d9df-4f11-87dd-ca2403efeeb9'	System	13 Dec 2020 09:01:15
User entered 'No (N)'	System	13 Dec 2020 09:01:15

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-13T02:01:08', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '7183ee3f-d9df-4f11-87dd-ca2403efeeb9'	System	13 Dec 2020 09:01:15
User entered 'No (N)'	System	13 Dec 2020 09:01:15

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-13T02:01:13', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '7183ee3f-d9df-4f11-87dd-ca2403efeeb9' User entered '13 Dec 2020 02:01:13'	System	13 Dec 2020 09:01:15
	System	13 Dec 2020 09:01:15

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-20T21:37:34', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0bca18cf-cd97-4451-8d7f-1b10c418478a' User entered 'No (N)'	System	21 Dec 2020 04:37:46
	System	21 Dec 2020 04:37:46

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-20T21:37:39', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0bca18cf-cd97-4451-8d7f-1b10c418478a' User entered 'No (N)'	System	21 Dec 2020 04:37:46
	System	21 Dec 2020 04:37:46

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-20T21:37:42', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '0bca18cf-cd97-4451-8d7f-1b10c418478a' User entered '20 Dec 2020 21:37:42'	System	21 Dec 2020 04:37:46
	System	21 Dec 2020 04:37:46

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-28T13:26:04', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '467912fc-f7ba-4cf5-a3d0-63712024b2c1' User entered 'No (N)'	System	28 Dec 2020 20:26:59
	System	28 Dec 2020 20:26:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-28T13:26:49', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '467912fc-f7ba-4cf5-a3d0-63712024b2c1' User entered 'No (N)'	System	28 Dec 2020 20:26:59
	System	28 Dec 2020 20:26:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2020-12-28T13:26:52', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '467912fc-f7ba-4cf5-a3d0-63712024b2c1' User entered '28 Dec 2020 13:26:52'	System	28 Dec 2020 20:26:59
	System	28 Dec 2020 20:26:59

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2021-01-03T12:32:21', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1ea9875d-9d9d-4ab8-b601-f7618a16270d' User entered 'No (N)'	System	03 Jan 2021 19:32:34
	System	03 Jan 2021 19:32:34

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2021-01-03T12:32:28', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1ea9875d-9d9d-4ab8-b601-f7618a16270d' User entered 'No (N)'	System	03 Jan 2021 19:32:34
	System	03 Jan 2021 19:32:34

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53944C00-D997-439F-B03E-474A3133AE88)', Time: '2021-01-03T12:32:31', User OID: 'PatientReportedOutcome (US3562040)', ODM File OID: '1ea9875d-9d9d-4ab8-b601-f7618a16270d' User entered '03 Jan 2021 12:32:31'	System	03 Jan 2021 19:32:34
	System	03 Jan 2021 19:32:34

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:51:06

US3562040

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:51:06
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:51:06

US3562040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:33
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 18:43:49

US3562040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:51:33
User entered '13 Nov 2020'	Dhwani Shah (b) (4)	13 Nov 2020 18:43:49

US3562040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:33
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 18:43:49

US3562040

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:33
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 18:43:49

US3562040

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:41
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 18:43:39

US3562040

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:30:39
User entered 'l'	System	13 Nov 2020 18:43:39

US3562040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:12:10
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 22:13:23

US3562040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:12:10
User entered empty.	Dhwani Shah (b) (4)	26 Jan 2021 22:13:23

US3562040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:12:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 22:13:23

US3562040

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:12:10
User entered empty.	Dhwani Shah (b) (4)	26 Jan 2021 22:13:23

US3562040

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:12:29
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 22:13:28

US3562040

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'l'	System	26 Jan 2021 22:13:28

US3562040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:13:23
User entered 'No (N)'	Dhwani Shah (b) (4)	26 Jan 2021 22:13:36

US3562040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:13:23
User entered empty.	Dhwani Shah (b) (4)	26 Jan 2021 22:13:36

US3562040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:13:23
User entered empty.	Dhwani Shah (b) (4)	26 Jan 2021 22:13:36

US3562040

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:13:23
User entered empty.	Dhwani Shah (b) (4)	26 Jan 2021 22:13:36

US3562040

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:13:30
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 22:13:45

US3562040

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	26 Jan 2021 22:13:45

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:53:19
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:59

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:19
User closed query 'Data is required. Please complete.' (Site from System).		08 Dec 2020 06:10:07
Query 'Data is required. Please complete.' answered with 'time is unknown' (Site from System).	Dhwani Shah (b) (4)	07 Dec 2020 14:58:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	07 Dec 2020 14:57:59
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 14:57:59
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	07 Dec 2020 14:57:59

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:53:19
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:59

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:19
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 14:57:59

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 1 (Day 1)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '26 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 03:20:46
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:54:07
Query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	20 Apr 2021 15:07:37
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
User opened query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:46:55
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Per CDM: Please check from log lines 1-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 10:11:13

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please check from log lines 1-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. ' answered with 'O2 AND TEMPRATURE ASSESMENT WAS NOT DONE ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	08 Jan 2021 22:01:50
User opened query 'Per CDM: Please check from log lines 1-6. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:09:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'I'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:54:09
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	20 Apr 2021 15:07:11
User entered empty.	System	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:54:11
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:07:11
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:47:40

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 2 (Day 2)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '27 Nov 2020'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 03:21:06
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:55:22
Query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	20 Apr 2021 15:08:25
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
User opened query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:47:10
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '1'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:55:24
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	20 Apr 2021 15:08:10
User entered empty.	System	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:55:26
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:08:10
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:38:47
User closed query 'Please confirm response. Per note on Safety Follow Up alert page in source, nasal congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). Query 'Please confirm response. Per note on Safety Follow Up alert page in source, nasal congestion appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	(b) (4)	23 Apr 2021 15:38:43
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:13:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:12:48
User opened query 'Please confirm response. Per note on Safety Follow Up alert page in source, nasal congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:56:41
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	22 Apr 2021 16:55:45
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 14:42:24
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:32:48

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:38:50
User closed query 'Please confirm response. Per note on Safety Follow Up alert page in source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).		23 Apr 2021 15:38:45
Query 'Please confirm response. Per note on Safety Follow Up alert page in source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:13:33
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:12:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:12:48
User opened query 'Please confirm response. Per note on Safety Follow Up alert page in source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 16:57:23
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:55:43
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:48:25

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:48:25

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 3 (Day 3)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '28 Nov 2020'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 03:21:22
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:39:11
Query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	20 Apr 2021 15:09:34
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
User opened query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:47:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '1'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:39:13
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	20 Apr 2021 15:09:16
User entered empty.	System	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:39:17
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:09:16
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:39:32
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	(b) (4)	23 Apr 2021 15:39:26
Signature has been broken.	Dhwani Shah (b) (4)	22 Apr 2021 19:18:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 19:17:06
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	Dhwani Shah (b) (4)	22 Apr 2021 19:17:06
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:59:16
User signature succeeded.	(b) (4), (b) (6)	22 Apr 2021 16:58:26
DataPoint Verified.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 17:32:48
	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:39:35
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).		23 Apr 2021 15:39:29
Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:18:24
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:17:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:17:06
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 16:59:40
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 16:58:28
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:02

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 4 (Day 4)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '29 Nov 2020'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 03:21:45
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:00:07
Query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	20 Apr 2021 15:10:51
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
User opened query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:47:41
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '1'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:00:16
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
Signature has been broken.	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	20 Apr 2021 15:10:34
User entered empty.	System	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:18
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:10:34
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:40:06
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:39:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	22 Apr 2021 19:24:02
Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	22 Apr 2021 19:24:02
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). DataPoint Un-verified.	Dhwani Shah (b) (4)	22 Apr 2021 19:23:42
	(b) (4), (b) (6)	22 Apr 2021 17:00:56
	(b) (4), (b) (6)	22 Apr 2021 17:00:33
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:40:09
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).		23 Apr 2021 15:40:02
Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:24:17
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:24:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:24:02
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:00:53
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:00:31
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:49:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 5 (Day 5)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '30 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 03:21:58
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:01:08
Query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:11:41
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:11:26
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:11:26
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:11:26
User opened query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:47:54
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '1'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:01:11
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:11:26
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:11:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:11:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	20 Apr 2021 15:11:26
User entered empty.	System	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:01:13
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:11:26
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:11:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:11:26
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:40:38
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	(b) (4)	23 Apr 2021 15:40:32
Signature has been broken.	Dhwani Shah (b) (4)	22 Apr 2021 19:25:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 19:24:59
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	Dhwani Shah (b) (4)	22 Apr 2021 19:24:59
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:01:29
User signature succeeded.	(b) (4)	22 Apr 2021 17:01:20
DataPoint Verified.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 17:32:48
	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:40:41
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).		23 Apr 2021 15:40:35
Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:25:35
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:24:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 19:24:59
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:01:44
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:01:22
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:50:26

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:50:26

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 6 (Day 6)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '01 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 03:22:11
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:01:57
Query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:12:54
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:12:37
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:12:37
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Apr 2021 15:12:37
User opened query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:48:10
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:01
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:12:37
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:12:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:12:37
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44
User entered '98'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	20 Apr 2021 15:12:37
User entered empty.	System	15 Dec 2020 15:56:44
User entered '%'	System	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:03
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Apr 2021 15:12:37
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:12:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Apr 2021 15:12:37
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44
User entered '98.7' F	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:55:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:41:10
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA). Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	(b) (4)	23 Apr 2021 15:41:03
Signature has been broken.	Dhwani Shah (b) (4)	22 Apr 2021 19:26:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 19:26:24
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	Dhwani Shah (b) (4)	22 Apr 2021 19:26:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:20
User signature succeeded.	(b) (4), (b) (6)	22 Apr 2021 17:02:12
DataPoint Verified.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 17:32:48
	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:41:13
User closed query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).		23 Apr 2021 15:41:06
Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	22 Apr 2021 19:27:06
Signature has been broken.	Dhwani Shah (b) (4)	22 Apr 2021 19:26:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	22 Apr 2021 19:26:24
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Runny Nose appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:02:58
Query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' canceled (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:02:38
User opened query 'Please confirm response. Per note on Safety Follow Up Alert in Source, Nasal Congestion appears to have started on 27Nov2020. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:02:33
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:13
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:55:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 7 (Day 7)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '02 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98.7' F	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:57:58
User closed query 'Please confirm response. Per source progress note, cough is lined through. Please update as applicable. ' (Site from CRA).	(b) (4)	16 Dec 2020 21:57:55
Query 'Please confirm response. Per source progress note, cough is lined through. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	16 Dec 2020 00:02:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:02:34
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User opened query 'Please confirm response. Per source progress note, cough is lined through. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:29:23
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:58:13
User closed query 'Please confirm response. Per source progress note, Loss of Taste is documented. Please update as applicable. ' (Site from CRA). Query 'Please confirm response. Per source progress note, Loss of Taste is documented. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	(b) (4)	16 Dec 2020 21:58:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Dec 2020 00:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:55
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User opened query 'Please confirm response. Per source progress note, Loss of Taste is documented. Please update as applicable. ' (Site from CRA). User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 17:30:48
	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:58:18
User closed query 'Please confirm response. Per source progress note, Loss of Smell is documented. Please update as applicable. ' (Site from CRA).	(b) (4)	16 Dec 2020 21:58:16
Query 'Please confirm response. Per source progress note, Loss of Smell is documented. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	16 Dec 2020 00:02:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:02:34
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User opened query 'Please confirm response. Per source progress note, Loss of Smell is documented. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:31:14
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:58:25
User closed query 'Please confirm response. Per source progress note, nasal congestion is documented. Please update as applicable. ' (Site from CRA).		16 Dec 2020 21:58:22
Query 'Please confirm response. Per source progress note, nasal congestion is documented. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:02:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:02:34
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User opened query 'Please confirm response. Per source progress note, nasal congestion is documented. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:31:49
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:58:31
User closed query 'Please confirm response. Per source progress note, runny nose is documented. Please update as applicable. ' (Site from CRA). Query 'Please confirm response. Per source progress note, runny nose is documented. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	(b) (4)	16 Dec 2020 21:58:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Dec 2020 00:03:00
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:33:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User opened query 'Please confirm response. Per source progress note, runny nose is documented. Please update as applicable. ' (Site from CRA). User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 17:32:17
	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:56:44

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 8 (Day 8)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '03 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98.7' F	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 15:57:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 9 (Day 9)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '04 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97.5' F	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:06:19

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 10 (Day 10)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '05 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '99'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97.6' F	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:07:34

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 11 (Day 11)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '06 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97.5' F	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:09:09

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 12 (Day 12)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '07 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98.5' F	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:59:46
User closed query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' (Site from CRA).		16 Dec 2020 21:59:41
Query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:03:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:03:29
User opened query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:39:43
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:38:48
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:59:51
User closed query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' (Site from CRA).		16 Dec 2020 21:59:48
Query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:03:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:03:29
User opened query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:39:50
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:38:50
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:11:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 13 (Day 13)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '08 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98.7' F	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:13:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 14 (Day 14)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '09 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98.5' F	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:00:12
User closed query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' (Site from CRA).		16 Dec 2020 22:00:09
Query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:03:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:03:51
User opened query 'Please confirm response. Per source, Mild is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:42:41
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:14:10

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 15 (Day 15)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '10 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97.5' F	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:15:28

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 16 (Day 16)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '11 Dec 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97.5' F	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:16:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:16:31

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 17 (Day 17)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '14 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '0'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '98'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered '97.1' F	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:32:48
User entered 'None (None)'	Dhwani Shah (b) (4)	15 Dec 2020 16:18:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 18 (Day 18)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered '15 Dec 2020'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered '0'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered '98'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '%'	System	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered '97.1' F	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Please add log lines for 12Dec2020 and 13Dec2020 telehealth visits that were NOT DONE and mark as "Assessment Not Done" per source. ' (Site from CRA).	(b) (4)	
Query 'Please add log lines for 12Dec2020 and 13Dec2020 telehealth visits that were NOT DONE and mark as "Assessment Not Done" per source. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:14:25
User opened query 'Please add log lines for 12Dec2020 and 13Dec2020 telehealth visits that were NOT DONE and mark as "Assessment Not Done" per source. ' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 20:28:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 17:57:47
	(b) (4), (b) (6)	01 Feb 2021 17:56:49
User entered 'None (None)'	Dhwani Shah (b) (4)	08 Jan 2021 22:03:00
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 19 (Day 19)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered '12 Dec 2020'	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered 'l'	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:25

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'Day 20 (Day 20)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered '13 Dec 2020'	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered 'l'	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:14:37
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 20:28:37

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User closed query 'Date of Visit is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
User opened query 'Date of Visit is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
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).		08 Dec 2020 06:08:14
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 'confirmed test was positive ' (Site from System).	Dhwani Shah (b) (4)	07 Dec 2020 14:58:35
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	07 Dec 2020 14:58:21
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User closed query 'Date of Test is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
User opened query 'Date of Test is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:58:41
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:53

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	07 Dec 2020 14:58:21

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Generated On: 11 Aug 2021 22:57:53

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:13:40
User closed query 'Please confirm response. No supporting documentation of ARDS in source. ' (Site from CRA).		12 Feb 2021 17:13:34
Query 'Please confirm response. No supporting documentation of ARDS in source. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	05 Feb 2021 00:04:34
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	05 Feb 2021 00:04:28
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:30
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User opened query 'Please confirm response. No supporting documentation of ARDS in source. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 18:04:13
User closed query 'Per CDM: It appears 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No but data is present. Please reconcile ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 10:16:08
Query 'Per CDM: It appears 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No but data is present. Please reconcile ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	08 Jan 2021 22:04:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	08 Jan 2021 22:04:51
User opened query 'Per CDM: It appears 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No but data is present. Please reconcile ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:51:29
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:13:47
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	05 Feb 2021 00:06:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:32
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered '08 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	08 Jan 2021 22:05:36
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

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Generated On: 11 Aug 2021 22:57:53

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:12

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

US3562040

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:25
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 22:27:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:57:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:03:21
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:27:19

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 3 (Day 3)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered '4 Dec 2020'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 5 (Day 5)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered '6 Dec 2020'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 7 (Day 7)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered '8 Dec 2020'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 9 (Day 9)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

US3562040

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:05:39
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 10DEC2020 for Day 9 is recorded in EDC, however sample is reported with 09DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).		24 Dec 2020 09:44:07
Query 'Per GCL Lab Recon: Saliva: Sample dated 10DEC2020 for Day 9 is recorded in EDC, however sample is reported with 09DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	22 Dec 2020 23:54:14
DataPoint Un-verified.	Dhwani Shah (b) (4)	22 Dec 2020 23:54:08
User entered '09 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	22 Dec 2020 23:54:08
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 10DEC2020 for Day 9 is recorded in EDC, however sample is reported with 09DEC2020 for Day 9 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:09:08
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered '10 Dec 2020'	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 14 (Day 14)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:07:20
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 23:59:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 23:59:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	15 Dec 2020 23:59:39
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:07:21
User entered empty.	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:07:22
User entered '15 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	15 Dec 2020 23:59:39
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:51
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered empty.	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 21 (Day 21)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:07:28
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 23:53:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 23:53:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	22 Dec 2020 23:53:19
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:07:21
User entered empty.	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:07:30
User entered '22 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	22 Dec 2020 23:53:19
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User entered empty.	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User accepted default value 'Day 28 (Day 28)'	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:07:37
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 22:40:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 22:40:51
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	04 Jan 2021 22:40:51
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:04
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:47:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:07:21
User entered empty.	Dhwani Shah (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:07:39
DataPoint Un-verified.		15 Dec 2020 17:48:06
DataPoint Verified.		15 Dec 2020 17:47:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:07:21

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:56:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:18

US3562040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:56:45
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:22:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	11 Dec 2020 17:06:53
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:11:48
User entered '2 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 14:57:18

US3562040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:56:45
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:18

US3562040

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'SICKD1'	System	07 Dec 2020 14:57:18

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:53:23
User closed query 'Please complete vital signs for Illness Visit Day 1 captured in source on Vital Sign page. ' (Site from CRA).		16 Dec 2020 22:00:49
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24
Query 'Please complete vital signs for Illness Visit Day 1 captured in source on Vital Sign page. ' answered with 'UPDATED' (Site from CRA).	(b) (4) Dhwani Shah (b) (4)	16 Dec 2020 00:00:45
User opened query 'Please complete vital signs for Illness Visit Day 1 captured in source on Vital Sign page. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:12:47

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '14:10'	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '2 Dec 2020 14:10'	System	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '64.8' in	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24
DataPoint set to visible.	(b) (4) System	07 Dec 2020 14:57:18

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '177.3' lb	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24
DataPoint set to visible.	(b) (4) System	07 Dec 2020 14:57:18

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '98.7' F	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered 'Oral (Oral)'	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered empty.	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '85'	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'bpm'	System	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '14'	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'breaths/min'	System	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '128'	Dhwani Shah (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'mmHg'	System	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:53:23
User entered '80'	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'mmHg'	System	16 Dec 2020 00:01:24

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:13:07
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:28

US3562040

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:13:07
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:28
	(b) (4)	

US3562040

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:57:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:13:25
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:41

US3562040

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:13:25
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	07 Dec 2020 14:57:41

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:49
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:41:09

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:49
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:09

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:49
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:09

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'SICKD28'	System	04 Jan 2021 22:41:09

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:04:57
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	04 Jan 2021 22:41:17

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:05:06
User entered 'No (N)'	Dhwani Shah (b) (4)	04 Jan 2021 22:41:28

US3562040

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:05:06
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:28

US3562040

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:57:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:05:13
User entered 'No (N)'	Dhwani Shah (b) (4)	04 Jan 2021 22:41:35

US3562040

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:05:13
User entered empty.	Dhwani Shah (b) (4)	04 Jan 2021 22:41:35

US3562040

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:57:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:06
DataPoint Un-verified.	Dhwani Shah (b) (4)	07 Dec 2020 14:58:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	07 Dec 2020 14:58:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:04:10
User entered 'No (N)'	Dhwani Shah (b) (4)	28 Aug 2020 00:24:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:38:14
DataPoint Verified.		15 Dec 2020 17:49:19
User entered 'USA-US071-2020-mRNA-1273-P301000006'	System	07 Dec 2020 21:16:32
User entered 'New'	(b) (4), (b) (6)	07 Dec 2020 21:16:32

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:21
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)	07 Dec 2020 15:04:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 15:04:44
Data point term sent to Coder	System	07 Dec 2020 15:03:59
User entered 'COVID 19 INFECTION'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:23
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:24
User entered 'No (N)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:49:26
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:32
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Un-verified.	Dhwani Shah (b) (4)	16 Dec 2020 00:40:24
User entered '26 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Dec 2020 00:40:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:32
User entered '2 Dec 2020'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:34
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:34
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Dec 2020 00:42:59
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:41
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:36
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:37
User closed query 'PV Query: Please confirm the event end date (considered when symptoms resolved). COVID-19 symptoms were still reported on 14 Dec 2020, however end date was reported as 08 Dec 2020.' (Site from Safety).		20 Jan 2021 13:37:53
Query 'PV Query: Please confirm the event end date (considered when symptoms resolved). COVID-19 symptoms were still reported on 14 Dec 2020, however end date was reported as 08 Dec 2020.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4)	15 Jan 2021 23:33:44
User entered '15 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	15 Jan 2021 23:33:36
User opened query 'PV Query: Please confirm the event end date (considered when symptoms resolved). COVID-19 symptoms were still reported on 14 Dec 2020, however end date was reported as 08 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:58:24
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)	16 Dec 2020 21:02:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4)	16 Dec 2020 00:43:05
User entered '08 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Dec 2020 00:42:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 17:05:36
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:39
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:49:58
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Dec 2020 15:03:38
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	07 Dec 2020 15:03:38
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Dec 2020 15:03:19
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:01
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:04
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:06
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:07
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:11
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:14
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:13
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:16
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:18
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:19
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:32
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:34
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:50
User closed query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		16 Dec 2020 18:31:20
Query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4)	16 Dec 2020 00:39:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:39:30
User opened query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 17:04:19
User entered 'None (NONE)'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:46
User entered 'l'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:47
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

US3562040

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:50:49
User entered '0'	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:08:55
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).		16 Dec 2020 18:31:29
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:43:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:42:59
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 17:05:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:57
User entered empty.	Dhwani Shah (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:09:00
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)	16 Dec 2020 18:31:49
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:31:39
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:31:35
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'swab result is already entered under covid 19 assesment ' (Site from Safety).	Dhwani Shah (b) (4)	16 Dec 2020 00:41:41
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 'none' (Site from Safety).	Dhwani Shah (b) (4)	16 Dec 2020 00:40:59
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4)	16 Dec 2020 00:40:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[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)	14 Dec 2020 17:06:08
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 17:05:17
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 17:04:38
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Dec 2020 15:03:38
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 15:03:38
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Dec 2020 15:03:19
User entered empty.	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '0'	System	07 Dec 2020 15:03:38
User entered '1'	System	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	07 Dec 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:57:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query 'Per CDM: Per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:55:54
Query 'Per CDM: Per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:31
User opened query 'Per CDM: Per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:22:12
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2 and 3, Diary Dose 2 Day 1 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:40:21

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 2 and 3, Diary Dose 2 Day 1 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'pt withdrew consent and pt is out of study. site is unable to varify with pt, please note all medication which was reported by pt has been entered in edc' (Site from DM).	Dhwani Shah (b) (4)	09 Feb 2021 22:24:11
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2 and 3, Diary Dose 2 Day 1 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 05:40:14
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:59:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:40:47

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (2 - (b) (4)	15 Aug 2020 00:22:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:58
Data point term sent to Coder	System	14 Aug 2020 23:41:59
User entered 'BUPROPION'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:41:26

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:41:26

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	09 Sep 2020 21:12:38
User entered 'DEPRESSION'	(b) (4), (b) (6)	09 Sep 2020 21:12:38
	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '300'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'mg (mg)'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'once daily (QD)'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	09 Sep 2020 21:12:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Sep 2020 21:12:38
	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	09 Sep 2020 21:12:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	16 Aug 2020 12:36:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 23:41:26
User entered 'UN UNK 2018'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '804 (804)'	System	14 Aug 2020 23:41:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:59
Data point term sent to Coder	System	14 Aug 2020 23:43:01
User entered 'SERTRALINE'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Conflicts with source, please confirm. Thank you!' (Site from CRA).	(b) (4)	23 Sep 2020 21:58:13
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 21:58:07
Query 'Conflicts with source, please confirm. Thank you!' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	13 Sep 2020 23:40:14
DataPoint Un-verified.	(b) (4)	
	Dhwani Shah (b) (4)	13 Sep 2020 23:40:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Sep 2020 23:40:05
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User opened query 'Conflicts with source, please confirm. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 21:07:15
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'DEPRESSION'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '100'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		16 Aug 2020 12:36:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 23:42:05
User entered 'UN UNK 2018'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '804 (804)'	System	14 Aug 2020 23:42:05

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:58
Data point term sent to Coder	System	14 Aug 2020 23:43:01
User entered 'VYVANSE'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Attention deficit hyperactivity disorder'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '50'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'mg (mg)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	09 Sep 2020 21:12:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Sep 2020 21:12:38
	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		16 Aug 2020 12:36:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 23:42:59
User entered 'UN UNK 2018'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered 'I'	System	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered '804 (804)'	System	14 Aug 2020 23:42:59

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 14:32:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 14:32:15
Data point term sent to Coder	System	14 Aug 2020 23:44:02
User entered 'CLONAZOPAM'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'ANXIETY'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0.5'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'as needed (PRN)'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		16 Aug 2020 12:36:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 23:43:58
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 23:43:58
User entered 'UN UNK 2019' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 23:43:58
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 23:43:46
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	14 Aug 2020 23:43:46

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:59
Data point term sent to Coder	System	14 Aug 2020 23:45:04
User entered 'CETIRIZINE'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:01:49
User closed query 'Conflicts with source, please confirm. Thank you!' (Site from CRA).	(b) (4)	21 Oct 2020 20:01:45
Query 'Conflicts with source, please confirm. Thank you!' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	25 Sep 2020 23:12:19
DataPoint Un-verified.	(b) (4)	25 Sep 2020 23:12:11
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	25 Sep 2020 23:12:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User opened query 'Conflicts with source, please confirm. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 21:09:20
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'SEASONAL ALLERGIES'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '10'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'mg (mg)'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'as needed (PRN)'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	09 Sep 2020 21:12:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	16 Aug 2020 12:36:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 23:45:02
User entered 'UN UNK 2010'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Source was error corrected to remove "yes", but "no" was never selected. Please confirm. Thank you!' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:02:07
Query 'Source was error corrected to remove "yes", but "no" was never selected. Please confirm. Thank you!' answered with 'confirmed as it is' (Site from CRA).	Dhwani Shah (b) (4)	25 Sep 2020 23:12:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User opened query 'Source was error corrected to remove "yes", but "no" was never selected. Please confirm. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 21:11:52
User entered 'No (N)'	Dhwani Shah (b) (4)	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	14 Aug 2020 23:45:02

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:42:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:42:26
Data point term sent to Coder	System	21 Aug 2020 20:42:08
User entered 'Ibuprofen'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Headaches'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '400'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	21 Aug 2020 20:41:12
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered empty.	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '14 Aug 2020'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '0'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	04 Jan 2021 22:45:14
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered '14 Aug 2020'	Dhwani Shah (b) (4)	21 Aug 2020 20:41:12
	(b) (4)	

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' answered with 'pt reported in diary and do not required seprate AE' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 04:23:42
	Dhwani Shah (b) (4)	17 Oct 2020 00:07:45

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:01:39
	(b) (4), (b) (6)	09 Sep 2020 21:12:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User entered 'l'	System	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User entered 'I'	System	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:23
User entered '804 (804)'	System	21 Aug 2020 20:41:12

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:55:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:55:15
Data point term sent to Coder	System	17 Oct 2020 00:10:03
User entered 'flu vaccine'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'flu prophylaxis'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'inejection'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'once (ONCE)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	04 Jan 2021 22:45:14
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered '08 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	18 Feb 2021 14:42:24
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:45:14
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Jan 2021 22:42:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered '08 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:11
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User entered empty.	System	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User entered empty.	System	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:58:28
User entered empty.	System	17 Oct 2020 00:09:55

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User closed query ' Per MM: Please confirm this event does not meet exclusion criteria # 4 (Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19).' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 05:14:35
User closed query 'Per MM, please review and confirm if the subject meets the criteria to continue with the original study SoEs per protocol 4.1.2. If no, please ensure a protocol deviation is captured (as appropriate)' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 02:38:47
Query 'Per MM, please review and confirm if the subject meets the criteria to continue with the original study SoEs per protocol 4.1.2. If no, please ensure a protocol deviation is captured (as appropriate)' answered with 'please rereview end of study page !Patient is already out from study. confirmed deviation was captured in subject source ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	26 Apr 2021 14:44:18
Query ' Per MM: Please confirm this event does not meet exclusion criteria # 4 (Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19).' answered with 'please rereview data ! pt was enrolled in study Aug2020 and received Pfizer EUA on Dec2021 which is after pt started study ! confirmed did not meet exclusion criteria # 4 ! ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	26 Apr 2021 14:43:01
User opened query ' Per MM: Please confirm this event does not meet exclusion criteria # 4 (Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19).' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 20:34:23

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per MM, please review and confirm if the subject meets the criteria to continue with the original study SoEs per protocol 4.1.2. If no, please ensure a protocol deviation is captured (as appropriate)' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 20:34:09
	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 22:16:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 22:16:59
Data point term sent to Coder	System	08 Apr 2021 22:15:43
User entered 'Pfizer EUA COVID 19 vaccine'	Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'Covid 19 prophylaxis'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered '0.3'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'mL (mL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'un Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'un Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:04:00
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:18:53
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User entered empty.	System	08 Apr 2021 22:15:22

US3562040

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:57:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 21:05:09
User entered 'No (N)'	Dhwani Shah (b) (4)	03 Sep 2020 01:00:11

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:10:25
User closed query 'Date of Study Discontinuation/Completion is prior to Date of Randomization. Please correct.' (Site from System).	System	04 Jan 2021 22:45:14
User closed query 'Date of Study Discontinuation/Completion is prior to Date of Informed Consent. Please correct.' (Site from System).	System	04 Jan 2021 22:45:14
User entered '04 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:45:14
User opened query 'Date of Study Discontinuation/Completion is prior to Date of Randomization. Please correct.' (Site from System).	System	04 Jan 2021 22:42:37
User opened query 'Date of Study Discontinuation/Completion is prior to Date of Informed Consent. Please correct.' (Site from System).	System	04 Jan 2021 22:42:37
User entered '04 Jan 2020'	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:03:22
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:01:01
User closed query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:22:18
Query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	07 Apr 2021 14:18:50
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Dhwani Shah (b) (4)	07 Apr 2021 14:18:33
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	07 Apr 2021 14:18:33
User opened query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:55:22
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:10:25
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Dhwani Shah (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:10:25
User entered 'PT RECEIVED PFIZER VACCINE DURING WEEKEND'	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:10:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:10:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:10:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:53

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:23:42
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:10:25
User entered empty.	Dhwani Shah (b) (4) (b) (4)	04 Jan 2021 22:42:37

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'USA-US071-2020-MRNA-1273-P301000006'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Joseph'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Davis'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '3900 E Camel Back road'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Phoenix'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '85018'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:38:22
DataPoint Verified.		15 Dec 2020 17:48:55
User entered 'US'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered '3'	(b) (4)	20 Jan 2021 13:38:29
User entered '2'	System	16 Dec 2020 18:32:10
User entered '1'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'USA-US071-2020-MRNA-1273-P301000006'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Joseph'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Davis'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '3900 E Camel Back road'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Phoenix'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 21:16:48
User entered '85018'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:38:22
DataPoint Verified.		15 Dec 2020 17:48:55
User entered 'US'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered '3'	(b) (4)	20 Jan 2021 13:38:29
User entered '2'	System	16 Dec 2020 18:32:10
User entered '1'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
User entered '07/Dec/2020 16:17'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:38:22
DataPoint Verified.		15 Dec 2020 17:48:55
User entered 'I'		07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'USA-US071-2020-MRNA-1273-P301000006'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4)	15 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Joseph'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Davis'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '3900 E Camel Back road'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Phoenix'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '85018'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:38:22
DataPoint Verified.		15 Dec 2020 17:48:55
User entered 'US'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered '3'	(b) (4)	20 Jan 2021 13:38:29
User entered '2'	System	16 Dec 2020 18:32:10
User entered '1'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:07:59
User entered '16/Dec/2020 13:32'	System	16 Dec 2020 18:32:10

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:01
Reviewed for Safety.		16 Dec 2020 18:32:15
User entered 'I'		16 Dec 2020 18:32:10

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'USA-US071-2020-MRNA-1273-P301000006'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'No (N)'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Joseph'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Davis'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '3900 E Camel Back road'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered 'Phoenix'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:48:55
Reviewed for Safety.		07 Dec 2020 21:16:48
User entered '85018'	System	07 Dec 2020 21:16:32

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:38:22
DataPoint Verified.		15 Dec 2020 17:48:55
User entered 'US'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Aug 2021 22:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
User entered '3'	(b) (4)	20 Jan 2021 13:38:29
User entered '2'	System	16 Dec 2020 18:32:10
User entered '1'	System	07 Dec 2020 21:17:01

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:12
User entered '20/Jan/2021 08:38'	System	20 Jan 2021 13:38:29

US3562040

Folder: SAE USA-US071-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:36
User signature succeeded.	Joseph Davis (b) (4)	18 Feb 2021 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 18:08:14
User entered 'l'		20 Jan 2021 13:38:29