

US3562015 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:56:17

All time stamps listed in this document are displayed in GMT

US3562015

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 20:59:40

Generated On: 11 Aug 2021 22:56:17

Participant ID

US3562015

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

US3562015

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3562015

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	48
Age Units	YEARS
Age (Derived)	48
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

US3562015

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Date of Informed Consent (<i>dd MMM yyyy</i>)	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3562015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3562015

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Were any significant conditions reported?

Yes ☒

No ☐

US3562015

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562015

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3562015

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3562015

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	EUGLYCEMIC DKA
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

US3562015

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

US3562015

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	VITAMIN D DEFICIENCY
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)	

US3562015

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3562015

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	FATTY LIVER
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)	_____

US3562015

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3562015

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	15:32 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 15:32
Height (xxx.x)	181 cm
Weight (xxx.x)	255 lb
BMI (xxx.x)	35.38021 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)	

US3562015

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3562015

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3562015

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

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)	True
Other	False
Specify	

US3562015

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

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

What was the participant's randomization number? 142941

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 ☒

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Height	ND - Not Done
Weight	ND - Not Done

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	15:32 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 15:32
Temperature (xxx.x)	99.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 17:00
Temperature (xxx.x)	99.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3562015

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

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.

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:31 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 16:31

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

US3562015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	06 AUG 2020
Collection time (00:00-23:59)	15:53 (24 HR)
Collection date and time (derived)	06 AUG 2020 15:53

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:58	06 AUG 2020 15:58
Nasopharyngeal Swab 2	No		

US3562015

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

99.0 °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

06 AUG 2020 17:00

PC Open Date & Time

06 AUG 2020 16:51

PC Close Date & Time

06 AUG 2020 19:21

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp	06 AUG 2020 20:38
PC Open Date & Time	06 AUG 2020 20:16
PC Close Date & Time	07 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

98.9 °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

07 AUG 2020 16:54

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 17:26

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 17:40

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

10 AUG 2020 18:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

11 AUG 2020 18:42

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

98.3 °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

12 AUG 2020 17:44

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 16:58

PC Open Date & Time

06 AUG 2020 16:51

PC Close Date & Time

06 AUG 2020 19:21

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 20:38

PC Open Date & Time

06 AUG 2020 20:16

PC Close Date & Time

07 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

07 AUG 2020 16:55

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

08 AUG 2020 17:27

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 17:40

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 18:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

12 AUG 2020 17:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:59
PC Open Date & Time	06 AUG 2020 16:51
PC Close Date & Time	06 AUG 2020 19:21

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 20:39
PC Open Date & Time	06 AUG 2020 20:16
PC Close Date & Time	07 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 2450

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	07 AUG 2020 16:55
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

54 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	08 AUG 2020 17:27
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

56 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	09 AUG 2020 17:41
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

58 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	10 AUG 2020 18:43
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

60 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	11 AUG 2020 18:41
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

62 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	12 AUG 2020 17:45
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3562015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:07

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:07

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:30
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	16:18 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 16:18
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3562015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 15:46 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 15:46

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

What was the frequency of the study treatment dosing? ONCE

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

US3562015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	15:13 (24 HR)
Collection date and time (derived)	3 SEP 2020 15:13

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	3 SEP 2020 15:20
Nasopharyngeal Swab 2	No		

US3562015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:19

PC Open Date & Time

03 SEP 2020 16:06

PC Close Date & Time

03 SEP 2020 18:36

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

98.1 °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	03 SEP 2020 19:40
PC Open Date & Time	03 SEP 2020 19:31
PC Close Date & Time	04 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

97.7 °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

04 SEP 2020 17:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

98.0 °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

05 SEP 2020 17:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

07 SEP 2020 18:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:07

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

03 SEP 2020 16:20

PC Open Date & Time

03 SEP 2020 16:06

PC Close Date & Time

03 SEP 2020 18:36

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:41

PC Open Date & Time

03 SEP 2020 19:31

PC Close Date & Time

04 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 17:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 18:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 18:07

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 16:20
PC Open Date & Time	03 SEP 2020 16:06
PC Close Date & Time	03 SEP 2020 18:36

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 19:41
PC Open Date & Time	03 SEP 2020 19:31
PC Close Date & Time	04 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 ☒

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	04 SEP 2020 17:50
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

100 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

		Yes ☐
PC Time stamp	05 SEP 2020 17:46	
PC Open Date & Time	05 SEP 2020 12:00	
PC Close Date & Time	06 SEP 2020 11:59	

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2450

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	06 SEP 2020 21:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

104 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	07 SEP 2020 18:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 ☒

PRODUCTION RELEASE (v12.003

106 of 2450

EAB) (1725)

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	08 SEP 2020 18:07
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 ☒

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

Yes ☐	
PC Time stamp	09 SEP 2020 19:07
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 10 SEP 2020 20:48

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3562015

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 20:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3562015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 14:18
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	106 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3562015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	14:40 (24 HR)
Collection date and time (derived)	1 OCT 2020 14:40

US3562015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:09

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

23 OCT 2020 19:43:44

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 05:41:29

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

14 NOV 2020 12:25:24

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 07:34:27
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

05 DEC 2020 19:26:08

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

12 DEC 2020 07:01:42

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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	20 DEC 2020 08:38:31
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

26 DEC 2020 00:09:04

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
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 ☒

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

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



Date and time of submission	02 JAN 2021 06:53:54
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 13:42:28
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 08:30:34

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 00:47:12

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 07:57:40
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 06:46:32

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 09:48:51
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 09:33:09

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 14:46:25

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 09:43:41

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:28:33

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3562015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:56:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 14:46:10

US3562015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:08

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:00:07

Generated On: 11 Aug 2021 22:56:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562015

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:00:07

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:13:17

Generated On: 11 Aug 2021 22:56:17

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 13:50
Temperature (xxx.x)	99.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3562015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	13:57 (24 HR)
Collection date and time (derived)	05 MAR 2021 13:57

US3562015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Date of Contact 30 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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	30 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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	01 JAN 2021

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.6 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

173 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	02 JAN 2021

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	98.3 F

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

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

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

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	03 JAN 2021

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.8 F

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

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

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

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	04 JAN 2021

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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

185 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	05 JAN 2021

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	99.5 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

189 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	06 JAN 2021

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	99.3 F

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

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

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

Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	07 JAN 2021

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	98.6 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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	08 JAN 2021

Assessment Not Done	False

O2 Saturation	92 %

O2 Saturation Units	%

Temperature	102.8 F

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

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

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

201 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	09 JAN 2021

Assessment Not Done	False

O2 Saturation	94 %

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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

205 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	10 JAN 2021

Assessment Not Done	False

O2 Saturation	96 %

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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

209 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	31 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

213 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	11 JAN 2021

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	98.6 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

217 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	12 JAN 2021

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	97.9 F

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

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

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

Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

221 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	13 JAN 2021

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	98.6 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

225 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	14 JAN 2021

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.6 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

229 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	15 JAN 2021

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.6 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

233 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	16 JAN 2021

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	98.6 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

237 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	17 JAN 2021

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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

Date	18 JAN 2021

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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

	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	☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Mar 2021 18:35:56

Generated On: 11 Aug 2021 22:56:17

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 ☐

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Date of Visit 31 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 31 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

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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 08 JAN 2021

End Date 09 JAN 2021

Oxygen Saturation 92 %

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 _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

249 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

250 of 2450

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 JAN 2021
Day 5	Yes	04 JAN 2021
Day 7	Yes	6 JAN 2021
Day 9	Yes	8 JAN 2021
Day 14	Yes	13 JAN 2021
Day 21	Yes	20 JAN 2021
Day 28	Yes	29 JAN 2021

US3562015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 DEC 2020
Time of assessment (00:00-23:59)	09:43 (24 HR)
Vital Signs Date and Time (derived)	31 DEC 2020 09:43
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 DEC 2020

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

US3562015

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 17 Feb 2021 20:59:43

Generated On: 11 Aug 2021 22:56:17

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

31 DEC 2020

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 13:31
Height (xxx.x)	71.2 in
Weight (xxx.x)	247 lb
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JAN 2021

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

US3562015

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 JAN 2021

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	15 FEB 2021

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

Folder OID	UNBLND_DECIDE

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	15 FEB 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☒
Placebo Only Flag	1
Continuing with mRNA-1273	

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	15 FEB 2021

Collection time (00:00-23:59)	13:53 (24 HR)

Collection date and time (derived)	15 FEB 2021 13:53

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	15 FEB 2021
Collection time (00:00 - 23:59)	13:55
Collection Date and Time (derived)	15 FEB 2021 13:55

US3562015

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 20:59:40

Generated On: 11 Aug 2021 22:56:17

AEID	USA-US071-2021-MRNA-1273-P30 1000002
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)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	18 JAN 2021
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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

267 of 2450

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 20:59:40

Generated On: 11 Aug 2021 22:56:17

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT WENT TO ER ON 1/8/21 TO EVALUATION OF SHORTNESS OF BREATH, OXIMETER HAS BEEN READING 93%, DONE CHEST XRAY AND ECGARDIOGRAM AT ER , PT WAS DISCHARGE WITHIN FEW HOURS

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 20:59:40

Generated On: 11 Aug 2021 22:56:17

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)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

Yes ☒

No ☐

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

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication METFORMIN HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

271 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 2011	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication ATORVASTATIN CALCIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

273 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 2014	
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	☒

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 0.4

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)

275 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 2014	
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	☒

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication ARIPIRAZOLE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 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)

277 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication SERTRALINE HCL

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 25

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)

279 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication TRADJENTA

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 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)

281 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 2014	
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	☒

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication LORATADINE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

283 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication FLUTICASONE PROPIONATE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL ALLERGIES

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

285 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 4

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)

287 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication BASAGLAR KWIKPEN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

289 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication TOUJEO

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

291 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

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

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication ZYRTEC D

Prophylaxis Yes ☐
No ☒

Indication COVID 19 INFECTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

293 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 17 JAN 2021		
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	☐

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication COVID 19 INFECTION

Dose per administration 600

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)

295 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 08 JAN 2021		
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	☐

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID 19 INFECTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

297 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 JAN 2021
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	☐

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Name of Medication BAMLANIVIMAB

Prophylaxis Yes ☐
No ☒

Indication COVID 19 INFECTION

Dose per administration 700/20

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

If dose unit is Other, specify MG/ML

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)

299 of 2450

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 JAN 2021
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	☐

US3562015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 20:59:41

Generated On: 11 Aug 2021 22:56:17

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

Date of study discontinuation/completion (dd MMM yyyy) 23 MAR 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

SPONSOR DECIDED LAST DOSE FOR STUDY VACCINE MARCH 25TH2021 AND PT RECEIVED MONOCONOL ANITBODIES AND NOT ELIGIBLE TO RECEIVE VACCINE TILL APR9TH2021. PT WITHDREW CONSENT

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	☐

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

SAEID	USA-US071-2021-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

SAEID	USA-US071-2021-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	11/JAN/2021 14:33
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

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

SAEID	USA-US071-2021-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	03/FEB/2021 14:10
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

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 18:35:58

Generated On: 11 Aug 2021 22:56:17

SAEID	USA-US071-2021-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	11/MAR/2021 16:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3562015 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562015

Form: Participant Creation

Generated On: 11 Aug 2021 22:56:17

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'US3562015'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:28

US3562015

Form: Participant Creation

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:18

US3562015

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:28

US3562015

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:18

US3562015

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'SCRN'	System	06 Aug 2020 22:56:18

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:29

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '48'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'YEARS'	System	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '48'	System	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Male (M)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:56:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:30:43

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Aug 2020'	System	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2020'	System	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Amendment 1 (1)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:45

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:28

US3562015

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:56:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	06 Aug 2020 22:56:52

US3562015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:56:52

US3562015

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:56:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:31:16

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 23:32:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 23:32:16
Data point term sent to Coder	System	07 Aug 2020 23:31:49
User entered 'Diabetes type 2'	Dhwani Shah (b) (4)	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2011'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2011'	System	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2011'	System	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:31:38

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
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)	07 Aug 2020 23:34:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 23:34:19
Data point term sent to Coder	System	07 Aug 2020 23:32:50
User entered 'Depression'	Dhwani Shah (b) (4)	07 Aug 2020 23:32:00
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2020'	System	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2020'	System	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:32:00

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 23:34:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 23:34:19
Data point term sent to Coder	System	07 Aug 2020 23:32:51
User entered 'enlarged prostate'	Dhwani Shah (b) (4)	07 Aug 2020 23:32:17
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2014'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2014'	System	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2014'	System	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:32:17

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
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)	07 Aug 2020 23:34:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 23:34:20
Data point term sent to Coder	System	07 Aug 2020 23:32:50
User entered 'seasonal allergies'	Dhwani Shah (b) (4)	07 Aug 2020 23:32:38
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2016'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2016'	System	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2016'	System	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	07 Aug 2020 23:32:38

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Euglycaemic diabetic ketoacidosis, LLT: Euglycemic diabetic ketoacidosis - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 07:41:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 07:41:14
Data point term sent to Coder	System	07 Aug 2020 23:33:51
User entered 'euglycemic DKA'	Dhwani Shah (b) (4)	07 Aug 2020 23:33:06
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un Feb 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	07 Aug 2020 23:33:37
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:37
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	07 Aug 2020 23:33:06
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un Feb 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Feb 2020'	System	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2020'	System	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Feb 2020'	System	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2020'	System	07 Aug 2020 23:33:06

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
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.	(b) (4) Coder Import (b) (4)	08 Sep 2020 23:05:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:05:53
Data point term sent to Coder	System	08 Sep 2020 23:04:25
User entered 'gastroesophageal reflux disease'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 1993'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 1993'	System	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '1993'	System	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:03:34

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 23:05:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 23:05:53
Data point term sent to Coder	System	08 Sep 2020 23:04:26
User entered 'internal hemorrhoids'	Dhwani Shah (b) (4)	08 Sep 2020 23:04:24
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un Jan 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un Jan 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2020'	System	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2020'	System	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2020'	System	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2020'	System	08 Sep 2020 23:04:24

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 23:06:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 23:06:54
Data point term sent to Coder	System	08 Sep 2020 23:05:27
User entered 'vitamin d deficiency'	Dhwani Shah (b) (4)	08 Sep 2020 23:04:42
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2017'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2017'	System	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2017'	System	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:04:42

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:06:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:06:55
Data point term sent to Coder	System	08 Sep 2020 23:05:27
User entered 'hyperlipidemia'	Dhwani Shah (b) (4)	08 Sep 2020 23:04:59
	(b) (4)	

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2014'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2014'	System	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2014'	System	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:04:59

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Sep 2020 23:06:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:06:54
Data point term sent to Coder	System	08 Sep 2020 23:05:27
User entered 'fatty liver'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2017'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2017'	System	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2017'	System	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:05:24

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:07:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:07:55
Data point term sent to Coder	System	08 Sep 2020 23:06:30
User entered 'sleep apnea'	Dhwani Shah (b) (4)	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'un UNK 2011'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'Jan 2011'	System	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2011'	System	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	08 Sep 2020 23:05:38

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:32'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '06 Aug 2020 15:32'	System	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '181' cm	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:35:12
DataPoint set to visible.	(b) (4) System	06 Aug 2020 22:56:52

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '255' lb	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:35:12
DataPoint set to visible.	(b) (4) System	06 Aug 2020 22:56:52

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: User entered '35.38021'	System	16 Sep 2020 23:46:38
User entered '35.4'	System	07 Aug 2020 23:35:12
DataPoint set to visible.	System	06 Aug 2020 22:56:52

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'kg/m2'	System	07 Aug 2020 23:35:12
DataPoint set to visible.	System	06 Aug 2020 22:56:52

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
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).	(b) (4), (b) (6)	27 Aug 2020 07:34:14
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)	25 Aug 2020 17:49:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:49:43
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 06:01:05
User entered '99.0' F	Dhwani Shah (b) (4)	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	25 Aug 2020 17:49:43
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:49:43
User entered '105'	Dhwani Shah (b) (4)	07 Aug 2020 23:35:12
	(b) (4)	

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'bpm'	System	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:49:43
User entered '16'	Dhwani Shah (b) (4)	07 Aug 2020 23:35:12
	(b) (4)	

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'breaths/min'	System	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:49:43
User entered '136'	Dhwani Shah (b) (4)	07 Aug 2020 23:35:12
	(b) (4)	

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:49:43
User entered '85'	Dhwani Shah (b) (4)	07 Aug 2020 23:35:12
	(b) (4)	

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	07 Aug 2020 23:35:12

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:33:20

US3562015

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:19:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 23:06:19
User entered '06 Aug 2020'	Dhwani Shah (b) (4)	07 Aug 2020 23:33:20

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:56:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:57:59

US3562015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:16

US3562015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:16

US3562015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:16

US3562015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'VISIT1'	System	06 Aug 2020 22:58:16

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:59:15

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:44:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:44:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 22:59:15
User entered '142941' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:59:15

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:59:15

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

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)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:56

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

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)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:56

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:56

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:56

US3562015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:56:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 22:58:56

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:56:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 03:20:57
Query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	03 Sep 2020 18:37:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 18:37:28
User opened query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 07:39:07
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	11 Aug 2020 19:37:17
User entered '71.2' in	Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:56:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	03 Sep 2020 18:37:28
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	11 Aug 2020 19:37:17
User entered '255' lb	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:56:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 03:20:57
Query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	03 Sep 2020 18:37:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 18:37:28
User opened query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 07:39:07
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	11 Aug 2020 19:37:17
User entered '71.2' in	Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:56:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	03 Sep 2020 18:37:28
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	11 Aug 2020 19:37:17
User entered '255' lb	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:32'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '06 Aug 2020 15:32'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '99.0' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '105'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'bpm'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'breaths/min'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '136'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '85'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:56:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 03:20:57
Query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	03 Sep 2020 18:37:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 18:37:28
User opened query 'Per CDM: Per CCGs pages 15-16, please update ND in the field response for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 07:39:07
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	11 Aug 2020 19:37:17
User entered '71.2' in	Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:56:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	03 Sep 2020 18:37:28
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4)	11 Aug 2020 19:37:17
User entered '255' lb	(b) (4) Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Per CDM: The treatment time on the Exposure CRF is 16:31 and the Vital Signs Post Dose Time of Assessment is 17:00 with a difference of 29 mins . Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	14 Aug 2020 09:33:08
Query 'Per CDM: The treatment time on the Exposure CRF is 16:31 and the Vital Signs Post Dose Time of Assessment is 17:00 with a difference of 29 mins . Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'Site coordinator inadvertently completed vital sign after 29 min instead of 30 min confirm as it is' (Site from DM).	Dhwani Shah (b) (4)	13 Aug 2020 14:00:38
User opened query 'Per CDM: The treatment time on the Exposure CRF is 16:31 and the Vital Signs Post Dose Time of Assessment is 17:00 with a difference of 29 mins . Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	10 Aug 2020 04:59:47
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 04:58:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol 60 min required' (Site from System).	Dhwani Shah (b) (4)	07 Aug 2020 23:38:47
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).		07 Aug 2020 23:38:30
User entered '17:00'	Dhwani Shah (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '06 Aug 2020 17:00'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '99.0' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '93'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'bpm'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'breaths/min'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '137'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '84'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	07 Aug 2020 23:38:30

US3562015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	11 Aug 2020 19:36:56
User entered 'Yes (Y)'	(b) (4)	
	Dhwani Shah (b) (4)	07 Aug 2020 23:35:31
	(b) (4)	

US3562015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty; reason for change Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	11 Aug 2020 19:36:56
User entered '06 Aug 2020'	(b) (4)	
	Dhwani Shah (b) (4)	07 Aug 2020 23:35:31
	(b) (4)	

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16:31'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '06 Aug 2020 16:31'	System	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'ONCE'	System	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 23:38:19

US3562015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:02

US3562015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:02

US3562015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:53'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:02

US3562015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '06 Aug 2020 15:53'	System	07 Aug 2020 23:36:02

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '06 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:58'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '06 Aug 2020 15:58'	System	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 19:50:59
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	05 Sep 2020 19:50:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	07 Aug 2020 23:36:43
	Dhwani Shah (b) (4)	07 Aug 2020 23:36:43
	(b) (4)	

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered empty.	System	07 Aug 2020 23:36:43

US3562015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	07 Aug 2020 23:36:50

US3562015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	07 Aug 2020 23:36:50

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T17:00:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '10a293e5-9e50-4ed4-a9f4-39ccab187123'	System	07 Aug 2020 00:01:04
User entered 'Yes (Y)'	System	07 Aug 2020 00:01:04

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T17:00:45', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '10a293e5-9e50-4ed4-a9f4-39ccab187123'	System	07 Aug 2020 00:01:04
User entered '99.0'	System	07 Aug 2020 00:01:04

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T17:00:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '10a293e5-9e50-4ed4-a9f4-39ccab187123'	System	07 Aug 2020 00:01:04
User entered 'No (N)'	System	07 Aug 2020 00:01:04

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T17:00:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '10a293e5-9e50-4ed4-a9f4-39ccab187123'	System	07 Aug 2020 00:01:04
User entered '06 Aug 2020 17:00'	System	07 Aug 2020 00:01:04

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 16:51'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 19:21'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:37:41', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9c6e3d1d-80ee-411b-8135-a3eecf12719f'	System	07 Aug 2020 03:38:06
User entered 'Yes (Y)'	System	07 Aug 2020 03:38:06

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:37:53', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9c6e3d1d-80ee-411b-8135-a3eecf12719f'	System	07 Aug 2020 03:38:06
User entered '98.4'	System	07 Aug 2020 03:38:06

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:37:57', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9c6e3d1d-80ee-411b-8135-a3eecf12719f'	System	07 Aug 2020 03:38:06
User entered 'No (N)'	System	07 Aug 2020 03:38:06

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:01', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9c6e3d1d-80ee-411b-8135-a3eecf12719f'	System	07 Aug 2020 03:38:06
User entered '06 Aug 2020 20:38'	System	07 Aug 2020 03:38:06

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 20:16'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 2'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:54:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3a34ff6c-8e89-4284-8ea5-2c11faacf796'	System	07 Aug 2020 23:54:58
User entered 'Yes (Y)'	System	07 Aug 2020 23:54:58

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:54:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3a34ff6c-8e89-4284-8ea5-2c11faacf796'	System	07 Aug 2020 23:54:58
User entered '98.9'	System	07 Aug 2020 23:54:58

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:54:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3a34ff6c-8e89-4284-8ea5-2c11faacf796'	System	07 Aug 2020 23:54:58
User entered 'No (N)'	System	07 Aug 2020 23:54:58

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:54:54', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3a34ff6c-8e89-4284-8ea5-2c11faaef796'	System	07 Aug 2020 23:54:58
User entered '07 Aug 2020 16:54'	System	07 Aug 2020 23:54:58

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 3'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:18', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'fb69024a-1149-4d70-aceb-b96bdc5704ff'	System	09 Aug 2020 00:26:35
User entered 'Yes (Y)'	System	09 Aug 2020 00:26:35

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'fb69024a-1149-4d70-aceb-b96bdc5704ff'	System	09 Aug 2020 00:26:35
User entered '98.5'	System	09 Aug 2020 00:26:35

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:26', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'fb69024a-1149-4d70-aceb-b96bdc5704ff'	System	09 Aug 2020 00:26:35
User entered 'No (N)'	System	09 Aug 2020 00:26:35

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:31', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'fb69024a-1149-4d70-aceb-b96bdc5704ff'	System	09 Aug 2020 00:26:35
User entered '08 Aug 2020 17:26'	System	09 Aug 2020 00:26:35

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 4'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:07', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1bc878a6-db0f-464b-98c4-2341935de773'	System	10 Aug 2020 00:40:28
User entered 'Yes (Y)'	System	10 Aug 2020 00:40:28

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:14', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1bc878a6-db0f-464b-98c4-2341935de773'	System	10 Aug 2020 00:40:28
User entered '98.3'	System	10 Aug 2020 00:40:28

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1bc878a6-db0f-464b-98c4-2341935de773'	System	10 Aug 2020 00:40:28
User entered 'No (N)'	System	10 Aug 2020 00:40:28

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:21', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1bc878a6-db0f-464b-98c4-2341935de773'	System	10 Aug 2020 00:40:28
User entered '09 Aug 2020 17:40'	System	10 Aug 2020 00:40:28

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 5'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9832443c-0017-4af4-9f6c-7743b6fbd7d2'	System	11 Aug 2020 01:42:40
User entered 'Yes (Y)'	System	11 Aug 2020 01:42:40

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9832443c-0017-4af4-9f6c-7743b6fbd7d2'	System	11 Aug 2020 01:42:40
User entered '97.7'	System	11 Aug 2020 01:42:40

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9832443c-0017-4af4-9f6c-7743b6fbd7d2'	System	11 Aug 2020 01:42:40
User entered 'No (N)'	System	11 Aug 2020 01:42:40

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:36', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '9832443c-0017-4af4-9f6c-7743b6fbd7d2'	System	11 Aug 2020 01:42:40
User entered '10 Aug 2020 18:42'	System	11 Aug 2020 01:42:40

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 6'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:42:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6d71d336-609e-47cc-b3fc-8168d2feff8c'	System	12 Aug 2020 01:42:55
User entered 'Yes (Y)'	System	12 Aug 2020 01:42:55

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:42:42', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6d71d336-609e-47cc-b3fc-8168d2feff8c'	System	12 Aug 2020 01:42:55
User entered '97.8'	System	12 Aug 2020 01:42:55

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:42:46', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6d71d336-609e-47cc-b3fc-8168d2feff8c'	System	12 Aug 2020 01:42:55
User entered 'No (N)'	System	12 Aug 2020 01:42:55

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:42:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6d71d336-609e-47cc-b3fc-8168d2feff8c'	System	12 Aug 2020 01:42:55
User entered '11 Aug 2020 18:42'	System	12 Aug 2020 01:42:55

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 7'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:22', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '274b8f2f-f37b-4efe-9401-ca5fbf051eb0'	System	13 Aug 2020 00:44:49
User entered 'Yes (Y)'	System	13 Aug 2020 00:44:49

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:28', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '274b8f2f-f37b-4efe-9401-ca5fbf051eb0'	System	13 Aug 2020 00:44:49
User entered '98.3'	System	13 Aug 2020 00:44:49

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '274b8f2f-f37b-4efe-9401-ca5fbf051eb0'	System	13 Aug 2020 00:44:49
User entered 'No (N)'	System	13 Aug 2020 00:44:49

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '274b8f2f-f37b-4efe-9401-ca5fbf051eb0'	System	13 Aug 2020 00:44:49
User entered '12 Aug 2020 17:44'	System	13 Aug 2020 00:44:49

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e47414f7-c4c1-4101-afb9-f41a664df547'	System	06 Aug 2020 23:58:42
User entered 'None (1)'	System	06 Aug 2020 23:58:42

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e47414f7-c4c1-4101-afb9-f41a664df547'	System	06 Aug 2020 23:58:42
User entered 'No (N)'	System	06 Aug 2020 23:58:42

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:26', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e47414f7-c4c1-4101-afb9-f41a664df547'	System	06 Aug 2020 23:58:42
User entered 'No (N)'	System	06 Aug 2020 23:58:42

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e47414f7-c4c1-4101-afb9-f41a664df547'	System	06 Aug 2020 23:58:42
User entered 'None (1)'	System	06 Aug 2020 23:58:42

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e47414f7-c4c1-4101-afb9-f41a664df547'	System	06 Aug 2020 23:58:42
User entered '06 Aug 2020 16:58'	System	06 Aug 2020 23:58:42

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 16:51'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 19:21'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:09', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '154ffd30-88ba-425c-8538-fd6916da2813'	System	07 Aug 2020 03:38:45
User entered 'None (1)'	System	07 Aug 2020 03:38:45

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '154ffd30-88ba-425c-8538-fd6916da2813'	System	07 Aug 2020 03:38:45
User entered 'No (N)'	System	07 Aug 2020 03:38:45

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '154ffd30-88ba-425c-8538-fd6916da2813'	System	07 Aug 2020 03:38:45
User entered 'No (N)'	System	07 Aug 2020 03:38:45

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '154ffd30-88ba-425c-8538-fd6916da2813'	System	07 Aug 2020 03:38:45
User entered 'None (1)'	System	07 Aug 2020 03:38:45

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '154ffd30-88ba-425c-8538-fd6916da2813'	System	07 Aug 2020 03:38:45
User entered '06 Aug 2020 20:38'	System	07 Aug 2020 03:38:45

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 20:16'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 2'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:54:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '561bc6ad-e0a4-4931-8521-24d96cad6ff4'	System	07 Aug 2020 23:55:19
User entered 'None (1)'	System	07 Aug 2020 23:55:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:02', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '561bc6ad-e0a4-4931-8521-24d96cad6ff4'	System	07 Aug 2020 23:55:19
User entered 'No (N)'	System	07 Aug 2020 23:55:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:05', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '561bc6ad-e0a4-4931-8521-24d96cad6ff4'	System	07 Aug 2020 23:55:19
User entered 'No (N)'	System	07 Aug 2020 23:55:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:12', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '561bc6ad-e0a4-4931-8521-24d96cad6ff4'	System	07 Aug 2020 23:55:19
User entered 'None (1)'	System	07 Aug 2020 23:55:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:15', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '561bc6ad-e0a4-4931-8521-24d96cad6ff4'	System	07 Aug 2020 23:55:19
User entered '07 Aug 2020 16:55'	System	07 Aug 2020 23:55:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 3'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:37', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ae8e8812-70e3-4dc0-9e09-1a903ead6528'	System	09 Aug 2020 00:27:12
User entered 'None (1)'	System	09 Aug 2020 00:27:12

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ae8e8812-70e3-4dc0-9e09-1a903ead6528'	System	09 Aug 2020 00:27:12
User entered 'No (N)'	System	09 Aug 2020 00:27:12

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:26:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ae8e8812-70e3-4dc0-9e09-1a903ead6528'	System	09 Aug 2020 00:27:12
User entered 'No (N)'	System	09 Aug 2020 00:27:12

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ae8e8812-70e3-4dc0-9e09-1a903ead6528'	System	09 Aug 2020 00:27:12
User entered 'None (1)'	System	09 Aug 2020 00:27:12

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:06', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ae8e8812-70e3-4dc0-9e09-1a903ead6528'	System	09 Aug 2020 00:27:12
User entered '08 Aug 2020 17:27'	System	09 Aug 2020 00:27:12

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 4'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ecb0afeb-97b4-4df4-a5b8-cc29c04524fd'	System	10 Aug 2020 00:41:00
User entered 'None (1)'	System	10 Aug 2020 00:41:00

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:36', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ecb0afeb-97b4-4df4-a5b8-cc29c04524fd'	System	10 Aug 2020 00:41:00
User entered 'No (N)'	System	10 Aug 2020 00:41:00

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ecb0afeb-97b4-4df4-a5b8-cc29c04524fd'	System	10 Aug 2020 00:41:00
User entered 'No (N)'	System	10 Aug 2020 00:41:00

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ecb0afeb-97b4-4df4-a5b8-cc29c04524fd'	System	10 Aug 2020 00:41:00
User entered 'None (1)'	System	10 Aug 2020 00:41:00

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:40:54', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'ecb0afeb-97b4-4df4-a5b8-cc29c04524fd'	System	10 Aug 2020 00:41:00
User entered '09 Aug 2020 17:40'	System	10 Aug 2020 00:41:00

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 5'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '96d30d08-5285-4725-a07b-03e86ef18b67'	System	11 Aug 2020 01:42:56
User entered 'None (1)'	System	11 Aug 2020 01:42:56

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:43', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '96d30d08-5285-4725-a07b-03e86ef18b67'	System	11 Aug 2020 01:42:56
User entered 'No (N)'	System	11 Aug 2020 01:42:56

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:45', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '96d30d08-5285-4725-a07b-03e86ef18b67'	System	11 Aug 2020 01:42:56
User entered 'No (N)'	System	11 Aug 2020 01:42:56

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:48', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '96d30d08-5285-4725-a07b-03e86ef18b67'	System	11 Aug 2020 01:42:56
User entered 'None (1)'	System	11 Aug 2020 01:42:56

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '96d30d08-5285-4725-a07b-03e86ef18b67'	System	11 Aug 2020 01:42:56
User entered '10 Aug 2020 18:42'	System	11 Aug 2020 01:42:56

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 6'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:43', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '565b3d96-5449-4d2e-bc03-7648a5031502'	System	12 Aug 2020 01:42:01
User entered 'None (1)'	System	12 Aug 2020 01:42:01

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:46', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '565b3d96-5449-4d2e-bc03-7648a5031502'	System	12 Aug 2020 01:42:01
User entered 'No (N)'	System	12 Aug 2020 01:42:01

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '565b3d96-5449-4d2e-bc03-7648a5031502'	System	12 Aug 2020 01:42:01
User entered 'No (N)'	System	12 Aug 2020 01:42:01

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:53', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '565b3d96-5449-4d2e-bc03-7648a5031502'	System	12 Aug 2020 01:42:01
User entered 'None (1)'	System	12 Aug 2020 01:42:01

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:57', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '565b3d96-5449-4d2e-bc03-7648a5031502'	System	12 Aug 2020 01:42:01
User entered '11 Aug 2020 18:41'	System	12 Aug 2020 01:42:01

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 7'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:51', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c57c99c7-fdd8-4927-9fd7-fb6c20399eb0'	System	13 Aug 2020 00:45:08
User entered 'None (1)'	System	13 Aug 2020 00:45:08

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:54', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c57c99c7-fdd8-4927-9fd7-fb6c20399eb0'	System	13 Aug 2020 00:45:08
User entered 'No (N)'	System	13 Aug 2020 00:45:08

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:44:57', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c57c99c7-fdd8-4927-9fd7-fb6c20399eb0'	System	13 Aug 2020 00:45:08
User entered 'No (N)'	System	13 Aug 2020 00:45:08

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c57c99c7-fdd8-4927-9fd7-fb6c20399eb0'	System	13 Aug 2020 00:45:08
User entered 'None (1)'	System	13 Aug 2020 00:45:08

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c57c99c7-fdd8-4927-9fd7-fb6c20399eb0'	System	13 Aug 2020 00:45:08
User entered '12 Aug 2020 17:45'	System	13 Aug 2020 00:45:08

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'None (0)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'None (0)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:52', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'None (0)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:58:58', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'None (0)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:59:01', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'None (0)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:59:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'None (0)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:59:09', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered 'No (N)'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T16:59:12', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2b554ff9-2d76-4e1e-9d94-1de2e0d91ba1'	System	06 Aug 2020 23:59:16
User entered '06 Aug 2020 16:59'	System	06 Aug 2020 23:59:16

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 16:51'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 19:21'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'None (0)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:38:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'None (0)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:39:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'None (0)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:39:21', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'None (0)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:39:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'None (0)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:39:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'None (0)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:39:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered 'No (N)'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-06T20:39:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '1f41aaa3-0373-4cbd-8fa9-949f752fa119'	System	07 Aug 2020 03:39:50
User entered '06 Aug 2020 20:39'	System	07 Aug 2020 03:39:50

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Aug 2020 20:16'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 2'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'None (0)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:22', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'None (0)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'None (0)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'None (0)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:31', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'None (0)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:33', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'None (0)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered 'No (N)'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-07T16:55:41', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7542544c-06ae-45f7-8347-779e546cf162'	System	07 Aug 2020 23:55:48
User entered '07 Aug 2020 16:55'	System	07 Aug 2020 23:55:48

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 3'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'None (0)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'None (0)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'None (0)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:18', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'None (0)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'None (0)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:22', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'None (0)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:28', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered 'No (N)'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-08T17:27:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6c181f6e-e170-40c1-8237-23136525e0ce'	System	09 Aug 2020 00:27:36
User entered '08 Aug 2020 17:27'	System	09 Aug 2020 00:27:36

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 4'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:04', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'No interference with activity (1)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:07', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'None (0)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'None (0)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:14', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'None (0)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'None (0)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:19', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'None (0)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:28', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered 'No (N)'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-09T17:41:37', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5f8799a7-6840-47ea-8b7c-e91eaf66e502'	System	10 Aug 2020 00:41:40
User entered '09 Aug 2020 17:41'	System	10 Aug 2020 00:41:40

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 5'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:55', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25eca7'	System	11 Aug 2020 01:43:29
User entered 'None (0)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:42:58', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25cca7'	System	11 Aug 2020 01:43:29
User entered 'None (0)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:43:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25eca7'	System	11 Aug 2020 01:43:29
User entered 'None (0)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:43:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25eca7'	System	11 Aug 2020 01:43:29
User entered 'None (0)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:43:05', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25cca7'	System	11 Aug 2020 01:43:29
User entered 'None (0)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:43:08', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25eca7'	System	11 Aug 2020 01:43:29
User entered 'None (0)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:43:21', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25eca7'	System	11 Aug 2020 01:43:29
User entered 'No (N)'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-10T18:43:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5edf2899-c98f-4ed1-8fe3-0068ee25eca7'	System	11 Aug 2020 01:43:29
User entered '10 Aug 2020 18:43'	System	11 Aug 2020 01:43:29

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 6'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:17', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'None (0)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'None (0)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'None (0)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'None (0)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'None (0)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'None (0)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:36', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered 'No (N)'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-11T18:41:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0fbc5f70-a551-44e0-842d-fba2d2de2889'	System	12 Aug 2020 01:41:45
User entered '11 Aug 2020 18:41'	System	12 Aug 2020 01:41:45

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 7'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:08', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'None (0)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'None (0)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'None (0)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'None (0)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:19', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'None (0)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:21', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'None (0)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered 'No (N)'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (937c2501023fc23a)', Time: '2020-08-12T17:45:30', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '64761217-1f1c-4269-a69b-cb843e26f7eb'	System	13 Aug 2020 00:45:33
User entered '12 Aug 2020 17:45'	System	13 Aug 2020 00:45:33

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:38:19

US3562015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:55:30

US3562015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '13 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:55:30

US3562015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:55:30

US3562015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:55:30

US3562015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:55:38

US3562015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	14 Aug 2020 14:55:38

US3562015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	20 Aug 2020 23:34:03

US3562015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '20 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	20 Aug 2020 23:34:03

US3562015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	20 Aug 2020 23:34:03

US3562015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	20 Aug 2020 23:34:03

US3562015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	20 Aug 2020 23:33:52

US3562015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	20 Aug 2020 23:33:52

US3562015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	27 Aug 2020 22:00:06

US3562015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '27 Aug 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	27 Aug 2020 22:00:06

US3562015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	27 Aug 2020 22:00:06

US3562015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	27 Aug 2020 22:00:06

US3562015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	27 Aug 2020 22:00:12

US3562015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	27 Aug 2020 22:00:12

US3562015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:06:19

US3562015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '3 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	08 Sep 2020 23:09:35
User entered '8 Sep 2020'	(b) (4)	
	Dhwani Shah (b) (4)	08 Sep 2020 23:06:19
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:06:19

US3562015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'VISIT2'	System	08 Sep 2020 23:06:19

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '3 Sep 2020' reason for change: Data Entry Error	System	08 Sep 2020 23:09:56
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Dhwani Shah (b) (4)	08 Sep 2020 23:09:56
User entered '8 Sep 2020'	(b) (4)	08 Sep 2020 23:09:35
	Dhwani Shah (b) (4)	08 Sep 2020 23:07:33
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
	System	08 Sep 2020 23:09:56
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	08 Sep 2020 23:07:33
User entered '14:30'	Dhwani Shah (b) (4)	08 Sep 2020 23:07:33
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '3 Sep 2020 14:30'	System	08 Sep 2020 23:09:56
User entered '8 Sep 2020 14:30'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '98.6' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '99'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'bpm'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'breaths/min'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '137'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '91'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '3 Sep 2020' reason for change: Data Entry Error	System	08 Sep 2020 23:09:56
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Dhwani Shah (b) (4)	08 Sep 2020 23:09:56
User entered '8 Sep 2020'	(b) (4)	08 Sep 2020 23:09:35
	Dhwani Shah (b) (4)	08 Sep 2020 23:07:33
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16:18'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '3 Sep 2020 16:18'	System	08 Sep 2020 23:09:56
User entered '8 Sep 2020 16:18'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '98.5' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '88'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'bpm'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'breaths/min'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '136'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '83'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	08 Sep 2020 23:07:33

US3562015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	20 Nov 2020 20:38:37
User entered 'No (N)'	(b) (4)	
	Dhwani Shah (b) (4)	08 Sep 2020 23:07:45
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	20 Nov 2020 20:38:37
User entered empty.	(b) (4)	
	Dhwani Shah (b) (4)	08 Sep 2020 23:07:45
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Sep 2020 23:09:35
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	08 Sep 2020 23:09:35
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 23:06:19
User entered '3 Sep 2020'	Dhwani Shah (b) (4)	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:46'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '3 Sep 2020 15:46'	System	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'ONCE'	System	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:56:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 22:56:49

US3562015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:25

US3562015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Sep 2020 23:10:36
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	08 Sep 2020 23:10:36
User entered '3 Sep 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	08 Sep 2020 23:10:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Sep 2020 23:10:25
User entered '8 Sep 2020'	System	08 Sep 2020 23:10:25
	Dhwani Shah (b) (4)	08 Sep 2020 23:10:25
	(b) (4)	

US3562015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:13'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:25

US3562015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '3 Sep 2020 15:13'	System	08 Sep 2020 23:10:36
User entered '8 Sep 2020 15:13'	System	08 Sep 2020 23:10:25

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '3 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '15:20'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '3 Sep 2020 15:20'	System	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered empty.	System	08 Sep 2020 23:10:52

US3562015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:10:59

US3562015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	08 Sep 2020 23:10:59

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T16:19:30', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e7c1d93c-0c02-44bb-be5a-636552502f49'	System	03 Sep 2020 23:19:53
User entered 'Yes (Y)'	System	03 Sep 2020 23:19:53

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T16:19:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e7c1d93c-0c02-44bb-be5a-636552502f49'	System	03 Sep 2020 23:19:53
User entered '98.5'	System	03 Sep 2020 23:19:53

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T16:19:42', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e7c1d93c-0c02-44bb-be5a-636552502f49'	System	03 Sep 2020 23:19:53
User entered 'No (N)'	System	03 Sep 2020 23:19:53

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:19:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e7c1d93c-0c02-44bb-be5a-636552502f49'	System	03 Sep 2020 23:19:53
User entered '03 Sep 2020 16:19'	System	03 Sep 2020 23:19:53

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 16:06'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 18:36'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T19:40:37', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26d72dc4-a4ae-4c4d-b6f2-84950cd686cb'	System	04 Sep 2020 02:40:54
User entered 'Yes (Y)'	System	04 Sep 2020 02:40:54

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:40:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26d72dc4-a4ae-4c4d-b6f2-84950cd686cb'	System	04 Sep 2020 02:40:54
User entered '98.1'	System	04 Sep 2020 02:40:54

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T19:40:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26d72dc4-a4ae-4c4d-b6f2-84950cd686cb'	System	04 Sep 2020 02:40:54
User entered 'No (N)'	System	04 Sep 2020 02:40:54

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T19:40:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26d72dc4-a4ae-4c4d-b6f2-84950cd686cb'	System	04 Sep 2020 02:40:54
User entered '03 Sep 2020 19:40'	System	04 Sep 2020 02:40:54

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 19:31'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 2'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:48:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f2116aff-2296-46cc-894e-1d05c938036e'	System	05 Sep 2020 00:49:07
User entered 'Yes (Y)'	System	05 Sep 2020 00:49:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:48:56', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f2116aff-2296-46cc-894e-1d05c938036e' User entered '97.7'	System	05 Sep 2020 00:49:07
	System	05 Sep 2020 00:49:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:48:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f2116aff-2296-46cc-894e-1d05c938036e'	System	05 Sep 2020 00:49:07
User entered 'No (N)'	System	05 Sep 2020 00:49:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f2116aff-2296-46cc-894e-1d05c938036e'	System	05 Sep 2020 00:49:07
User entered '04 Sep 2020 17:49'	System	05 Sep 2020 00:49:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 3'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:44:54', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c0a3beb2-fb29-4de4-be25-c741e610dd88'	System	06 Sep 2020 00:45:29
User entered 'Yes (Y)'	System	06 Sep 2020 00:45:29

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:45:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c0a3beb2-fb29-4de4-be25-c741e610dd88'	System	06 Sep 2020 00:45:29
User entered '98.0'	System	06 Sep 2020 00:45:29

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:45:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c0a3beb2-fb29-4de4-be25-c741e610dd88'	System	06 Sep 2020 00:45:29
User entered 'No (N)'	System	06 Sep 2020 00:45:29

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:45:26', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c0a3beb2-fb29-4de4-be25-c741e610dd88'	System	06 Sep 2020 00:45:29
User entered '05 Sep 2020 17:45'	System	06 Sep 2020 00:45:29

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 4'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c773bd03-c810-4e99-8731-3b0f86020b2c'	System	07 Sep 2020 04:53:28
User entered 'Yes (Y)'	System	07 Sep 2020 04:53:28

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:21', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c773bd03-c810-4e99-8731-3b0f86020b2c' User entered '98.5'	System	07 Sep 2020 04:53:28
	System	07 Sep 2020 04:53:28

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c773bd03-c810-4e99-8731-3b0f86020b2c'	System	07 Sep 2020 04:53:28
User entered 'No (N)'	System	07 Sep 2020 04:53:28

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:26', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c773bd03-c810-4e99-8731-3b0f86020b2c'	System	07 Sep 2020 04:53:28
User entered '06 Sep 2020 21:53'	System	07 Sep 2020 04:53:28

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 5'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:15:51', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e790flaa-b441-4181-adbd-27c9c6fa53e9'	System	08 Sep 2020 01:16:10
User entered 'Yes (Y)'	System	08 Sep 2020 01:16:10

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-07T18:15:57', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e790flaa-b441-4181-adbd-27c9c6fa53e9'	System	08 Sep 2020 01:16:10
User entered '98.1'	System	08 Sep 2020 01:16:10

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-07T18:16:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e790f1aa-b441-4181-adbd-27c9c6fa53e9'	System	08 Sep 2020 01:16:10
User entered 'No (N)'	System	08 Sep 2020 01:16:10

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:07', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e790flaa-b441-4181-adbd-27c9c6fa53e9'	System	08 Sep 2020 01:16:10
User entered '07 Sep 2020 18:16'	System	08 Sep 2020 01:16:10

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 6'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:05:42', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6465e0e1-6819-46ef-8eac-449d2094b147'	System	09 Sep 2020 01:07:07
User entered 'Yes (Y)'	System	09 Sep 2020 01:07:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:06:53', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6465e0e1-6819-46ef-8eac-449d2094b147'	System	09 Sep 2020 01:07:07
User entered '98.5'	System	09 Sep 2020 01:07:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:06:58', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6465e0e1-6819-46ef-8eac-449d2094b147'	System	09 Sep 2020 01:07:07
User entered 'No (N)'	System	09 Sep 2020 01:07:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6465e0e1-6819-46ef-8eac-449d2094b147'	System	09 Sep 2020 01:07:07
User entered '08 Sep 2020 18:07'	System	09 Sep 2020 01:07:07

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 7'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-09T19:06:01', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6127748d-d8df-4421-8e58-f1bcf151c96f'	System	10 Sep 2020 02:06:37
User entered 'Yes (Y)'	System	10 Sep 2020 02:06:37

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:06:17', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6127748d-d8df-4421-8e58-f1bcf151c96f' User entered '98.0'	System	10 Sep 2020 02:06:37
	System	10 Sep 2020 02:06:37

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:06:31', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6127748d-d8df-4421-8e58-f1bcf151c96f'	System	10 Sep 2020 02:06:37
User entered 'No (N)'	System	10 Sep 2020 02:06:37

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-09T19:06:34', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6127748d-d8df-4421-8e58-f1bcf151c96f'	System	10 Sep 2020 02:06:37
User entered '09 Sep 2020 19:06'	System	10 Sep 2020 02:06:37

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:08', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0aed4c31-0440-4924-b7a7-8887d76ad494'	System	03 Sep 2020 23:20:27
User entered 'None (1)'	System	03 Sep 2020 23:20:27

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:12', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0aed4c31-0440-4924-b7a7-8887d76ad494'	System	03 Sep 2020 23:20:27
User entered 'No (N)'	System	03 Sep 2020 23:20:27

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0aed4c31-0440-4924-b7a7-8887d76ad494'	System	03 Sep 2020 23:20:27
User entered 'No (N)'	System	03 Sep 2020 23:20:27

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:22', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0aed4c31-0440-4924-b7a7-8887d76ad494'	System	03 Sep 2020 23:20:27
User entered 'None (1)'	System	03 Sep 2020 23:20:27

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0aed4c31-0440-4924-b7a7-8887d76ad494' User entered '03 Sep 2020 16:20'	System	03 Sep 2020 23:20:27
	System	03 Sep 2020 23:20:27

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 16:06'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 18:36'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:40:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7ac2a8dc-9bbe-48b0-9a3e-434b9d990379'	System	04 Sep 2020 02:41:34
User entered 'None (1)'	System	04 Sep 2020 02:41:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T19:41:06', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7ac2a8dc-9bbe-48b0-9a3e-434b9d990379'	System	04 Sep 2020 02:41:34
User entered 'No (N)'	System	04 Sep 2020 02:41:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-03T19:41:15', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7ac2a8dc-9bbe-48b0-9a3e-434b9d990379'	System	04 Sep 2020 02:41:34
User entered 'No (N)'	System	04 Sep 2020 02:41:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7ac2a8dc-9bbe-48b0-9a3e-434b9d990379'	System	04 Sep 2020 02:41:34
User entered 'None (1)'	System	04 Sep 2020 02:41:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7ac2a8dc-9bbe-48b0-9a3e-434b9d990379'	System	04 Sep 2020 02:41:34
User entered '03 Sep 2020 19:41'	System	04 Sep 2020 02:41:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 19:31'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 2'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:07', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd2e4599d-abd4-44bc-9ac6-1bb29055713b'	System	05 Sep 2020 00:49:37
User entered 'None (1)'	System	05 Sep 2020 00:49:37

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd2e4599d-abd4-44bc-9ac6-1bb29055713b'	System	05 Sep 2020 00:49:37
User entered 'No (N)'	System	05 Sep 2020 00:49:37

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:14', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd2e4599d-abd4-44bc-9ac6-1bb29055713b'	System	05 Sep 2020 00:49:37
User entered 'No (N)'	System	05 Sep 2020 00:49:37

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd2e4599d-abd4-44bc-9ac6-1bb29055713b'	System	05 Sep 2020 00:49:37
User entered 'None (1)'	System	05 Sep 2020 00:49:37

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-04T17:49:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd2e4599d-abd4-44bc-9ac6-1bb29055713b'	System	05 Sep 2020 00:49:37
User entered '04 Sep 2020 17:49'	System	05 Sep 2020 00:49:37

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 3'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:45:41', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b1cc5603-8f69-4704-bf86-c45618f89838'	System	06 Sep 2020 00:45:59
User entered 'None (1)'	System	06 Sep 2020 00:45:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:45:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b1cc5603-8f69-4704-bf86-c45618f89838'	System	06 Sep 2020 00:45:59
User entered 'No (N)'	System	06 Sep 2020 00:45:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:45:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b1cc5603-8f69-4704-bf86-c45618f89838'	System	06 Sep 2020 00:45:59
User entered 'No (N)'	System	06 Sep 2020 00:45:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:45:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b1cc5603-8f69-4704-bf86-c45618f89838'	System	06 Sep 2020 00:45:59
User entered 'None (1)'	System	06 Sep 2020 00:45:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:45:53', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b1cc5603-8f69-4704-bf86-c45618f89838'	System	06 Sep 2020 00:45:59
User entered '05 Sep 2020 17:45'	System	06 Sep 2020 00:45:59

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 4'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:30', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7c0db97d-cb14-44e0-b55f-a6fdbcf54b4c'	System	07 Sep 2020 04:53:41
User entered 'None (1)'	System	07 Sep 2020 04:53:41

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:33', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7c0db97d-cb14-44e0-b55f-a6fdbcf54b4c'	System	07 Sep 2020 04:53:41
User entered 'No (N)'	System	07 Sep 2020 04:53:41

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7c0db97d-cb14-44e0-b55f-a6fdbcf54b4c'	System	07 Sep 2020 04:53:41
User entered 'No (N)'	System	07 Sep 2020 04:53:41

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7c0db97d-cb14-44e0-b55f-a6fdbcf54b4c'	System	07 Sep 2020 04:53:41
User entered 'None (1)'	System	07 Sep 2020 04:53:41

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7c0db97d-cb14-44e0-b55f-a6fdbcf54b4c'	System	07 Sep 2020 04:53:41
User entered '06 Sep 2020 21:53'	System	07 Sep 2020 04:53:41

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 5'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-07T18:16:12', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c8dd0760-f60a-4ee4-bf6d-1e1bd2da5022'	System	08 Sep 2020 01:16:34
User entered 'None (1)'	System	08 Sep 2020 01:16:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:14', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c8dd0760-f60a-4ee4-bf6d-1e1bd2da5022'	System	08 Sep 2020 01:16:34
User entered 'No (N)'	System	08 Sep 2020 01:16:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-07T18:16:23', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c8dd0760-f60a-4ee4-bf6d-1e1bd2da5022'	System	08 Sep 2020 01:16:34
User entered 'No (N)'	System	08 Sep 2020 01:16:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-07T18:16:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c8dd0760-f60a-4ee4-bf6d-1e1bd2da5022'	System	08 Sep 2020 01:16:34
User entered 'None (1)'	System	08 Sep 2020 01:16:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-07T18:16:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c8dd0760-f60a-4ee4-bf6d-1e1bd2da5022'	System	08 Sep 2020 01:16:34
User entered '07 Sep 2020 18:16'	System	08 Sep 2020 01:16:34

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 6'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:07', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c51be2a1-1954-4506-91b8-1431a7b2cf84'	System	09 Sep 2020 01:07:18
User entered 'None (1)'	System	09 Sep 2020 01:07:18

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:09', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c51be2a1-1954-4506-91b8-1431a7b2cf84'	System	09 Sep 2020 01:07:18
User entered 'No (N)'	System	09 Sep 2020 01:07:18

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:11', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c51be2a1-1954-4506-91b8-1431a7b2cf84'	System	09 Sep 2020 01:07:18
User entered 'No (N)'	System	09 Sep 2020 01:07:18

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-08T18:07:14', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c51be2a1-1954-4506-91b8-1431a7b2cf84'	System	09 Sep 2020 01:07:18
User entered 'None (1)'	System	09 Sep 2020 01:07:18

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c51be2a1-1954-4506-91b8-1431a7b2cf84'	System	09 Sep 2020 01:07:18
User entered '08 Sep 2020 18:07'	System	09 Sep 2020 01:07:18

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 7'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:06:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b98e48b6-400d-44f3-b9ce-8de9a7f98b35'	System	10 Sep 2020 02:06:53
User entered 'None (1)'	System	10 Sep 2020 02:06:53

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-09T19:06:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b98e48b6-400d-44f3-b9ce-8de9a7f98b35'	System	10 Sep 2020 02:06:53
User entered 'No (N)'	System	10 Sep 2020 02:06:53

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-09T19:06:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b98e48b6-400d-44f3-b9ce-8de9a7f98b35'	System	10 Sep 2020 02:06:53
User entered 'No (N)'	System	10 Sep 2020 02:06:53

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-09T19:06:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b98e48b6-400d-44f3-b9ce-8de9a7f98b35'	System	10 Sep 2020 02:06:53
User entered 'None (1)'	System	10 Sep 2020 02:06:53

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:06:51', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b98e48b6-400d-44f3-b9ce-8de9a7f98b35'	System	10 Sep 2020 02:06:53
User entered '09 Sep 2020 19:06'	System	10 Sep 2020 02:06:53

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:30', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'None (0)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'None (0)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:34', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'None (0)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:36', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'None (0)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'None (0)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'None (0)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:46', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered 'No (N)'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T16:20:48', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '119455a2-85f8-4896-a759-f2c1b02615a8'	System	03 Sep 2020 23:20:53
User entered '03 Sep 2020 16:20'	System	03 Sep 2020 23:20:53

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 16:06'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 18:36'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:33', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'None (0)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'None (0)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'None (0)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'None (0)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:43', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'None (0)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:46', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'None (0)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:52', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered 'No (N)'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-03T19:41:58', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'b9b7e4af-0eb6-4c72-9ea7-b1128b109f69'	System	04 Sep 2020 02:42:01
User entered '03 Sep 2020 19:41'	System	04 Sep 2020 02:42:01

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '03 Sep 2020 19:31'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 2'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-04T17:49:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered 'None (0)'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered 'None (0)'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered 'None (0)'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b' User entered 'None (0)'	System	05 Sep 2020 00:50:05
	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:46', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered 'None (0)'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:49:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered 'None (0)'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-04T17:49:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered 'No (N)'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-04T17:50:02', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5c836a6b-86e3-471b-ba11-cb4aba12479b'	System	05 Sep 2020 00:50:05
User entered '04 Sep 2020 17:50'	System	05 Sep 2020 00:50:05

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 3'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:45:58', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'None (0)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:46:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'None (0)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:46:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'None (0)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-05T17:46:05', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'None (0)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:46:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'None (0)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:46:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'None (0)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:46:18', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered 'No (N)'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-05T17:46:22', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5534af16-e0fc-45d0-8a3c-1993cbeb460d'	System	06 Sep 2020 00:46:26
User entered '05 Sep 2020 17:46'	System	06 Sep 2020 00:46:26

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 4'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'None (0)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-09-06T21:53:45', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'None (0)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'None (0)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'None (0)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:52', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'None (0)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:54', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'None (0)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:57', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered 'No (N)'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-06T21:53:59', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2c7412c1-82a9-4627-9d9b-1abb16989e57'	System	07 Sep 2020 04:54:02
User entered '06 Sep 2020 21:53'	System	07 Sep 2020 04:54:02

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 5'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:33', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'None (0)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'None (0)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:37', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'None (0)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'None (0)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:41', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'None (0)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'None (0)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:47', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered 'No (N)'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-07T18:16:50', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6809bbd6-656b-4729-9808-b54ac680d96d'	System	08 Sep 2020 01:16:52
User entered '07 Sep 2020 18:16'	System	08 Sep 2020 01:16:52

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 6'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'None (0)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:22', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'None (0)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'None (0)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:26', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'None (0)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:28', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'None (0)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:30', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'None (0)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered 'No (N)'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-08T18:07:37', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'df346cee-59ed-4710-b840-818f6dd78275'	System	09 Sep 2020 01:07:42
User entered '08 Sep 2020 18:07'	System	09 Sep 2020 01:07:42

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	03 Sep 2020 22:56:49
User entered 'Day 7'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:06:57', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'No interference with activity (1)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'None (0)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'None (0)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:06', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'None (0)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:09', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'None (0)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:13', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'None (0)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered 'No (N)'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-09T19:07:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'db591214-7104-429a-a48f-87da8b5a3aa3'	System	10 Sep 2020 02:07:30
User entered '09 Sep 2020 19:07'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:56:49

US3562015

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	10 Sep 2020 02:07:30
User entered 'Day 8'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:56:17

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-10T20:48:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5b0f094a-6872-4660-a17e-6e47b804c985'	System	11 Sep 2020 03:48:34
User entered 'None (0)'	System	11 Sep 2020 03:48:34

US3562015

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:56:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-10T20:48:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '5b0f094a-6872-4660-a17e-6e47b804c985'	System	11 Sep 2020 03:48:34
User entered '10 Sep 2020 20:48'	System	11 Sep 2020 03:48:34

US3562015

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	10 Sep 2020 02:07:30
User entered 'Day 8'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:56:17

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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-10T20:48:34', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c2d65d80-0dc1-4e32-9d7d-23b6f7cf291e'	System	11 Sep 2020 03:48:40
User entered 'No (N)'	System	11 Sep 2020 03:48:40

US3562015

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:56:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-09-10T20:48:37', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c2d65d80-0dc1-4e32-9d7d-23b6f7cf291e'	System	11 Sep 2020 03:48:40
User entered '10 Sep 2020 20:48'	System	11 Sep 2020 03:48:40

US3562015

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:56:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 02:07:30

US3562015

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:56:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 02:07:30

US3562015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Sep 2020 18:26:12

US3562015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '10 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Sep 2020 18:26:12

US3562015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Sep 2020 18:26:12

US3562015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Sep 2020 18:26:12

US3562015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Sep 2020 18:26:19

US3562015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	14 Sep 2020 18:26:19

US3562015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:37:48

US3562015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '17 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:37:48

US3562015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:37:48

US3562015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:37:48

US3562015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:37:56

US3562015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	24 Sep 2020 20:37:56

US3562015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:38:12

US3562015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '24 Sep 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:38:12

US3562015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:38:12

US3562015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:38:12

US3562015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Sep 2020 20:38:23

US3562015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	24 Sep 2020 20:38:23

US3562015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:58:56

US3562015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:58:56

US3562015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:58:56

US3562015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'VISIT3'	System	02 Oct 2020 13:58:56

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '14:18'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '1 Oct 2020 14:18'	System	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '98.8' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '106'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'bpm'	System	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'breaths/min'	System	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '137'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '81'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'mmHg'	System	02 Oct 2020 14:00:19

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11

US3562015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11

US3562015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	20 Nov 2020 20:38:54
User entered 'No (N)'	(b) (4)	
	Dhwani Shah (b) (4)	02 Oct 2020 13:59:11
	(b) (4)	

US3562015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	20 Nov 2020 20:38:54
User entered empty.	(b) (4)	
	Dhwani Shah (b) (4)	02 Oct 2020 13:59:11
	(b) (4)	

US3562015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:59:37

US3562015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '1 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:59:37

US3562015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '14:40'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:59:37

US3562015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered '1 Oct 2020 14:40'	System	02 Oct 2020 13:59:37

US3562015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 13:59:02

US3562015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'I'	System	02 Oct 2020 13:59:02

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 64'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 71'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 78'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-10-23T19:43:36', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7b7dbec6-f0e8-40b6-8433-01fa7ed3427b'	System	24 Oct 2020 02:43:47
User entered 'No (N)'	System	24 Oct 2020 02:43:47

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-10-23T19:43:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7b7dbec6-f0e8-40b6-8433-01fa7ed3427b'	System	24 Oct 2020 02:43:47
User entered 'No (N)'	System	24 Oct 2020 02:43:47

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-10-23T19:43:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7b7dbec6-f0e8-40b6-8433-01fa7ed3427b'	System	24 Oct 2020 02:43:47
User entered '23 Oct 2020 19:43:44'	System	24 Oct 2020 02:43:47

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 92'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-11-03T05:41:10', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26385a74-7abf-4d7b-9861-43f57ce44915'	System	03 Nov 2020 12:41:31
User entered 'No (N)'	System	03 Nov 2020 12:41:31

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-11-03T05:41:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26385a74-7abf-4d7b-9861-43f57ce44915'	System	03 Nov 2020 12:41:31
User entered 'No (N)'	System	03 Nov 2020 12:41:31

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-11-03T05:41:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '26385a74-7abf-4d7b-9861-43f57ce44915'	System	03 Nov 2020 12:41:31
User entered '03 Nov 2020 05:41:29'	System	03 Nov 2020 12:41:31

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 99'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-11-14T12:25:16', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '676299f7-6d08-499e-b409-ff02a3c7fd2c'	System	14 Nov 2020 19:25:27
User entered 'No (N)'	System	14 Nov 2020 19:25:27

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-11-14T12:25:21', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '676299f7-6d08-499e-b409-ff02a3c7fd2c'	System	14 Nov 2020 19:25:27
User entered 'No (N)'	System	14 Nov 2020 19:25:27

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-11-14T12:25:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '676299f7-6d08-499e-b409-ff02a3c7fd2c' User entered '14 Nov 2020 12:25:24'	System	14 Nov 2020 19:25:27
	System	14 Nov 2020 19:25:27

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:53:21
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered 'Day 106'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 23:38:19

US3562015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:42
Data entry locked.	System	06 Aug 2020 23:38:19
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 23:38:19

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-11-21T07:34:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '4345d78c-c983-4859-adda-311980d875f5'	System	21 Nov 2020 14:34:30
User entered 'No (N)'	System	21 Nov 2020 14:34:30

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-11-21T07:34:24', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '4345d78c-c983-4859-adda-311980d875f5'	System	21 Nov 2020 14:34:30
User entered 'No (N)'	System	21 Nov 2020 14:34:30

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-11-21T07:34:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '4345d78c-c983-4859-adda-311980d875f5' User entered '21 Nov 2020 07:34:27'	System	21 Nov 2020 14:34:30
	System	21 Nov 2020 14:34:30

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Please 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Please 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Please 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-12-05T19:26:02', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'effb2354-77ad-456e-a0c5-c865d3df909f'	System	06 Dec 2020 02:26:12
User entered 'No (N)'	System	06 Dec 2020 02:26:12

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-12-05T19:26:05', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'effb2354-77ad-456e-a0c5-c865d3df909f'	System	06 Dec 2020 02:26:12
User entered 'No (N)'	System	06 Dec 2020 02:26:12

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-12-05T19:26:08', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'effb2354-77ad-456e-a0c5-c865d3df909f' User entered '05 Dec 2020 19:26:08'	System	06 Dec 2020 02:26:12
	System	06 Dec 2020 02:26:12

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-12-12T07:01:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'a97adbd5-772b-456b-8d92-62aae9359a2f'	System	12 Dec 2020 14:01:44
User entered 'No (N)'	System	12 Dec 2020 14:01:44

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-12-12T07:01:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'a97adbd5-772b-456b-8d92-62aae9359a2f'	System	12 Dec 2020 14:01:44
User entered 'No (N)'	System	12 Dec 2020 14:01:44

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-12-12T07:01:42', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'a97adbd5-772b-456b-8d92-62aae9359a2f' User entered '12 Dec 2020 07:01:42'	System	12 Dec 2020 14:01:44
	System	12 Dec 2020 14:01:44

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-12-20T08:38:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'a3e251db-77c6-4e69-a226-7c7fa1d85351'	System	20 Dec 2020 15:38:34
User entered 'No (N)'	System	20 Dec 2020 15:38:34

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-12-20T08:38:29', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'a3e251db-77c6-4e69-a226-7c7fa1d85351'	System	20 Dec 2020 15:38:34
User entered 'No (N)'	System	20 Dec 2020 15:38:34

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-12-20T08:38:31', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'a3e251db-77c6-4e69-a226-7c7fa1d85351'	System	20 Dec 2020 15:38:34
User entered '20 Dec 2020 08:38:31'	System	20 Dec 2020 15:38:34

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-12-26T00:08:56', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd942807b-5b71-4f67-a05f-b2cc03e697df'	System	26 Dec 2020 07:09:09
User entered 'No (N)'	System	26 Dec 2020 07:09:09

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2020-12-26T00:09:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd942807b-5b71-4f67-a05f-b2cc03e697df'	System	26 Dec 2020 07:09:09
User entered 'No (N)'	System	26 Dec 2020 07:09:09

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2020-12-26T00:09:04', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'd942807b-5b71-4f67-a05f-b2cc03e697df' User entered '26 Dec 2020 00:09:04'	System	26 Dec 2020 07:09:09
	System	26 Dec 2020 07:09:09

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:52:56', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'Yes (Y)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:03', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'Yes (Y)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:11', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:20', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'Yes (Y)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7' User entered '0'	System	02 Jan 2021 13:54:06
	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eaceea7'	System	02 Jan 2021 13:54:06
User entered '1'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eaceea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7' User entered '1'	System	02 Jan 2021 13:54:06
	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eaceea7'	System	02 Jan 2021 13:54:06
User entered '1'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7' User entered '0'	System	02 Jan 2021 13:54:06
	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eaceea7'	System	02 Jan 2021 13:54:06
User entered '1'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eaceea7' User entered '0'	System	02 Jan 2021 13:54:06
	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:39', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '0'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-02T06:53:42', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:46', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'Yes (Y)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:49', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-02T06:53:54', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '6ea90c2a-ef10-4cd4-a2f5-c02317eacea7'	System	02 Jan 2021 13:54:06
User entered '02 Jan 2021 06:53:54'	System	02 Jan 2021 13:54:06

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-13T13:42:14', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f1b0ea14-1106-452b-938f-8950c1db9917'	System	13 Jan 2021 20:42:36
User entered 'No (N)'	System	13 Jan 2021 20:42:36

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-13T13:42:18', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f1b0ea14-1106-452b-938f-8950c1db9917'	System	13 Jan 2021 20:42:36
User entered 'Yes (Y)'	System	13 Jan 2021 20:42:36

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Please 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-13T13:42:25', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f1b0ea14-1106-452b-938f-8950c1db9917'	System	13 Jan 2021 20:42:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 20:42:36

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-13T13:42:28', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'f1b0ea14-1106-452b-938f-8950c1db9917'	System	13 Jan 2021 20:42:36
User entered '13 Jan 2021 13:42:28'	System	13 Jan 2021 20:42:36

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-20T08:30:26', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e3df7cbe-4629-4fd1-a655-b3b368f3bd53'	System	20 Jan 2021 15:30:37
User entered 'No (N)'	System	20 Jan 2021 15:30:37

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-20T08:30:31', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e3df7cbe-4629-4fd1-a655-b3b368f3bd53'	System	20 Jan 2021 15:30:37
User entered 'No (N)'	System	20 Jan 2021 15:30:37

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-20T08:30:34', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e3df7cbe-4629-4fd1-a655-b3b368f3bd53'	System	20 Jan 2021 15:30:37
User entered '20 Jan 2021 08:30:34'	System	20 Jan 2021 15:30:37

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-23T00:47:05', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'edbfaf0b-60bc-4b68-b671-930d59f07be6'	System	23 Jan 2021 07:47:16
User entered 'No (N)'	System	23 Jan 2021 07:47:16

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-01-23T00:47:09', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'edbfaf0b-60bc-4b68-b671-930d59f07be6'	System	23 Jan 2021 07:47:16
User entered 'No (N)'	System	23 Jan 2021 07:47:16

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-01-23T00:47:12', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'edbfaf0b-60bc-4b68-b671-930d59f07be6'	System	23 Jan 2021 07:47:16
User entered '23 Jan 2021 00:47:12'	System	23 Jan 2021 07:47:16

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-03T07:57:35', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2654e2d1-006e-49a3-b563-5206e68751a8'	System	03 Feb 2021 14:57:48
User entered 'No (N)'	System	03 Feb 2021 14:57:48

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-03T07:57:38', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2654e2d1-006e-49a3-b563-5206e68751a8'	System	03 Feb 2021 14:57:48
User entered 'No (N)'	System	03 Feb 2021 14:57:48

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-03T07:57:40', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '2654e2d1-006e-49a3-b563-5206e68751a8' User entered '03 Feb 2021 07:57:40'	System	03 Feb 2021 14:57:48
	System	03 Feb 2021 14:57:48

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-02-06T06:46:23', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0982b681-c487-4549-bcba-04e658e75fe1'	System	06 Feb 2021 13:46:35
User entered 'No (N)'	System	06 Feb 2021 13:46:35

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-06T06:46:27', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0982b681-c487-4549-bcba-04e658e75fe1'	System	06 Feb 2021 13:46:35
User entered 'No (N)'	System	06 Feb 2021 13:46:35

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-06T06:46:32', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '0982b681-c487-4549-bcba-04e658e75fe1' User entered '06 Feb 2021 06:46:32'	System	06 Feb 2021 13:46:35
	System	06 Feb 2021 13:46:35

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-02-13T09:48:42', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7895b306-a5bc-4082-94cc-52c049cffbe8'	System	13 Feb 2021 16:48:54
User entered 'No (N)'	System	13 Feb 2021 16:48:54

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-13T09:48:44', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7895b306-a5bc-4082-94cc-52c049cffbe8'	System	13 Feb 2021 16:48:54
User entered 'No (N)'	System	13 Feb 2021 16:48:54

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-13T09:48:51', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '7895b306-a5bc-4082-94cc-52c049cffbe8'	System	13 Feb 2021 16:48:54
User entered '13 Feb 2021 09:48:51'	System	13 Feb 2021 16:48:54

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-02-21T09:33:04', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '30ea2e80-7850-4f3f-be8e-062a6ad42b5f'	System	21 Feb 2021 16:33:11
User entered 'No (N)'	System	21 Feb 2021 16:33:11

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-21T09:33:06', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '30ea2e80-7850-4f3f-be8e-062a6ad42b5f'	System	21 Feb 2021 16:33:11
User entered 'No (N)'	System	21 Feb 2021 16:33:11

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-02-21T09:33:09', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '30ea2e80-7850-4f3f-be8e-062a6ad42b5f' User entered '21 Feb 2021 09:33:09'	System	21 Feb 2021 16:33:11
	System	21 Feb 2021 16:33:11

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-03T14:46:16-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3870e35f-e6ba-4790-a2df-0a26b7deaafd'	System	03 Mar 2021 21:46:33
User entered 'No (N)'	System	03 Mar 2021 21:46:33

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-03T14:46:22-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3870e35f-e6ba-4790-a2df-0a26b7deaafd'	System	03 Mar 2021 21:46:33
User entered 'No (N)'	System	03 Mar 2021 21:46:33

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-03-03T14:46:25-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: '3870e35f-e6ba-4790-a2df-0a26b7deaafd' User entered '03 Mar 2021 14:46:25'	System	03 Mar 2021 21:46:33
	System	03 Mar 2021 21:46:33

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-06T09:43:36-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e437c4b9-ca9d-4fc3-a427-29d25307575e' User entered 'No (N)'	System	06 Mar 2021 16:43:45
	System	06 Mar 2021 16:43:45

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-03-06T09:43:38-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e437c4b9-ca9d-4fc3-a427-29d25307575e'	System	06 Mar 2021 16:43:45
User entered 'No (N)'	System	06 Mar 2021 16:43:45

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-06T09:43:41-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'e437c4b9-ca9d-4fc3-a427-29d25307575e' User entered '06 Mar 2021 09:43:41'	System	06 Mar 2021 16:43:45
	System	06 Mar 2021 16:43:45

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-13T08:28:24-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c20ea671-d8c9-4084-b56e-8225aac42e46'	System	13 Mar 2021 15:28:37
User entered 'No (N)'	System	13 Mar 2021 15:28:37

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-13T08:28:29-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c20ea671-d8c9-4084-b56e-8225aac42e46'	System	13 Mar 2021 15:28:37
User entered 'No (N)'	System	13 Mar 2021 15:28:37

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfdb361)', Time: '2021-03-13T08:28:33-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'c20ea671-d8c9-4084-b56e-8225aae42e46' User entered '13 Mar 2021 08:28:33'	System	13 Mar 2021 15:28:37
	System	13 Mar 2021 15:28:37

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Have you been exposed to someone with 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Please 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Please 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

Please 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)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:23:42

US3562015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:56:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:42
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:23:42

US3562015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:56:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-03-03T14:46:07-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'bb789740-db2c-40d6-9843-3dfa72b88467'	System	03 Mar 2021 21:46:14
User entered 'No (N)'	System	03 Mar 2021 21:46:14

US3562015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:56:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03188757ddfb361)', Time: '2021-03-03T14:46:10-07:00', User OID: 'PatientReportedOutcome (US3562015)', ODM File OID: 'bb789740-db2c-40d6-9843-3dfa72b88467' User entered '03 Mar 2021 14:46:10'	System	03 Mar 2021 21:46:14
	System	03 Mar 2021 21:46:14

US3562015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:43:36

US3562015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:43:36

US3562015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:43:36

US3562015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:43:36

US3562015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:43:42

US3562015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 04:08:11
User entered 'l'	System	29 Oct 2020 21:43:42

US3562015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 31-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	19 Jan 2021 10:52:53
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 31-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	Dhwani Shah (b) (4)	13 Jan 2021 23:55:26
' answered with 'PLEASE CHECK COVID DIAGNOSTIC TEST ! ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 31-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	05 Jan 2021 07:55:18
' (Site from DM). User entered 'Yes (Y)'	Dhwani Shah (b) (4)	03 Dec 2020 16:47:34

US3562015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '2 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 16:47:34

US3562015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 16:47:34

US3562015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 16:47:34

US3562015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 16:47:39

US3562015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	03 Dec 2020 16:47:39

US3562015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:55:46

US3562015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:55:46

US3562015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:55:46

US3562015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:55:46

US3562015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:55:51

US3562015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	01 Feb 2021 18:55:51

US3562015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:56:13

US3562015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 15-FEB-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 15-FEB-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:53:19
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 15-FEB-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 15-FEB-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:25:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 15-FEB-2021 is reported under Participant Decision Visit/OL-D1 in PPD portal; however, swab sample for 15-FEB-2021 is missing in EDC. Kindly review if the swab sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:00:13
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 21:00:09
User entered '01 Feb 2021'	Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:56:13

US3562015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:56:13

US3562015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:56:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered empty.	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:56:13

US3562015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 21:00:09
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	01 Feb 2021 18:56:19

US3562015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	01 Feb 2021 18:56:19

US3562015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:25:28

US3562015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '05 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:25:28

US3562015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:25:28

US3562015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'VISIT4'	System	05 Mar 2021 22:25:28

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '05 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '13:50'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '05 Mar 2021 13:50'	System	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '99.0' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '97'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'bpm'	System	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'breaths/min'	System	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '124'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	07 Apr 2021 21:13:17
User entered '85'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	29 Mar 2021 19:59:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:26:00

US3562015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '05 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:26:00

US3562015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:25:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:50:52
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'updated EDC' (Site from DM).	Dhwani Shah (b) (4)	08 Mar 2021 15:27:52
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:53:04
User entered '05 Mar 2021'	Dhwani Shah (b) (4)	05 Mar 2021 22:25:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '13:57'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Mar 2021 22:25:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '05 Mar 2021 13:57'	System	05 Mar 2021 22:25:50

US3562015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 15:03:12
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	05 Mar 2021 22:26:11
	(b) (4)	

US3562015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:56:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	24 Mar 2021 15:03:12
User entered 'l'	System	05 Mar 2021 22:26:11

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:56:17

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:50
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:01
User entered '30 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:26

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:56:17

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:50
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:01
User closed query 'Data is required. Please complete.' (Site from System).		11 Jan 2021 10:15:16
Query 'Data is required. Please complete.' answered with 'UNKNOWN' (Site from System).	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:33
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 15:57:26
User entered empty.	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:26

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:50
Data hard locked.		26 Apr 2021 19:22:18
User entered empty.	System	07 Jan 2021 15:57:26

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:56:17

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:50
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:01
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:26

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:50
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:01
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:26

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 1 (Day 1)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per ETRTR: Please add log line and details for 31Dec20, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:06:21
DataPoint Verified.		01 Feb 2021 16:55:43
Query 'Per ETRTR: Please add log line and details for 31Dec20, thanks.' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	28 Jan 2021 00:09:27
User opened query 'Per ETRTR: Please add log line and details for 31Dec20, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:02:53
User entered '30 Dec 2020'	Dhwani Shah (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	13 Jan 2021 23:58:53
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	13 Jan 2021 23:58:53
User entered empty.	System	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	13 Jan 2021 23:58:53
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:15:54

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 2 (Day 2)'	Dhwani Shah (b) (4)	11 Jan 2021 14:19:27
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '01 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:06:37
User closed query 'Please confirm response. Per source, NONE is marked. Please update as applicable. ' (Site from CRA).		12 Feb 2021 17:06:34
Query 'Please confirm response. Per source, NONE is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:52:16
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:52:10
User opened query 'Please confirm response. Per source, NONE is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:00:18
DataPoint Un-verified.		01 Feb 2021 16:59:58
DataPoint Verified.		01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:19:27

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 3 (Day 3)'	Dhwani Shah (b) (4)	11 Jan 2021 14:21:45
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '02 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '99'	Dhwani Shah (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.3' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 4 (Day 4)'	Dhwani Shah (b) (4)	11 Jan 2021 19:38:34
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '03 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97'	Dhwani Shah (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.8' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:38:34

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 5 (Day 5)'	Dhwani Shah (b) (4)	11 Jan 2021 19:40:42
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '04 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97.5' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:40:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 6 (Day 6)'	Dhwani Shah (b) (4)	11 Jan 2021 19:42:13
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '05 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '96'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '99.5' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:07:06
User closed query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).		12 Feb 2021 17:07:00
Query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:52:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:52:33
User opened query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:07:26
DataPoint Un-verified.		01 Feb 2021 17:04:58
DataPoint Verified.		01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:07:09
User closed query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:07:03
Query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 17:52:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 17:52:33
User opened query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:07:34
DataPoint Un-verified.		01 Feb 2021 17:05:00
DataPoint Verified.		01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:42:13

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 7 (Day 7)'	Dhwani Shah (b) (4)	11 Jan 2021 19:45:52
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '06 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '96'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '99.3' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:07:28
User closed query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).		12 Feb 2021 17:07:23
Query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:54:55
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:54:51
User opened query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:09:12
DataPoint Un-verified.		01 Feb 2021 17:08:58
DataPoint Verified.		01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:07:31
User closed query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:07:25
Query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 17:54:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	01 Feb 2021 17:54:51
User opened query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:09:19
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 17:09:02
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:07:38
User closed query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4)	12 Feb 2021 17:07:35
Query 'Please confirm response. Per source, Mild is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 17:55:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 17:54:51
User opened query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:10:07
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 17:09:48
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:45:52

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 8 (Day 8)'	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '07 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:07:56
User closed query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:07:53
Query 'Please confirm response. Per source, Mild is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 17:54:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 17:54:32
User opened query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:11:50
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 17:11:34
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:47:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 9 (Day 9)'	(b) (4) Dhwani Shah (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '08 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '92'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '102.8' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:49:42

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:02
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 10 (Day 10)'	(b) (4)	
	Dhwani Shah (b) (4)	11 Jan 2021 19:51:35
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '09 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '94'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'		11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.7' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:19
User closed query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).		12 Feb 2021 17:08:16
Query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:54:18
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:54:13
User opened query 'Please confirm response. Per source, Moderate is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:13:49
DataPoint Un-verified.		01 Feb 2021 17:13:41
DataPoint Verified.		01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:08:26
User closed query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:08:23
Query 'Please confirm response. Per source, Mild is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 17:54:22
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	01 Feb 2021 17:54:13
User opened query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:15:02
DataPoint Un-verified.		01 Feb 2021 17:14:47
DataPoint Verified.		01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:51:35

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:19:23
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:19:23
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 11 (Day 11)'	Dhwani Shah (b) (4)	11 Jan 2021 19:53:51
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per ETRTR: Please add log lines for days after 10Jan21. Per CCG's, expected data entry in this page is every 24hrs, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:08:57
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
Query 'Per ETRTR: Please add log lines for days after 10Jan21. Per CCG's, expected data entry in this page is every 24hrs, thanks.' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	28 Jan 2021 00:18:26
User opened query 'Per ETRTR: Please add log lines for days after 10Jan21. Per CCG's, expected data entry in this page is every 24hrs, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:03:38
User entered '10 Jan 2021'	Dhwani Shah (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '96'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.7' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	11 Jan 2021 19:53:51

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4)	
	Dhwani Shah (b) (4)	19 Mar 2021 15:18:24
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	19 Mar 2021 15:18:24
User signature succeeded.	(b) (4)	
	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered 'Day 12 (Day 12)'	Dhwani Shah (b) (4)	28 Jan 2021 00:10:48
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User closed query 'Per CDM RQ: Response noted. However the date for line 12 appears to be off sequence. Please verify and update data accordingly. (Site from DM).		22 Mar 2021 05:23:01
Query 'Per CDM RQ: Response noted. However the date for line 12 appears to be off sequence. Please verify and update data accordingly.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	19 Mar 2021 15:19:37
User opened query 'Per CDM RQ: Response noted. However the date for line 12 appears to be off sequence. Please verify and update data accordingly. (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 03:08:05
User closed query 'Per CDM: Per sponsor review, please verify data and if appropriate, update "Date" for line 12 on Symptom Log, since it appears to be off sequence. Else clarify. ' (Site from DM).		19 Mar 2021 03:08:05
Query 'Per CDM: Per sponsor review, please verify data and if appropriate, update "Date" for line 12 on Symptom Log, since it appears to be off sequence. Else clarify. ' answered with 'confirmed as it is !missed to add 31dec2020 after 30dec2020 and added here ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	17 Mar 2021 22:41:28
User opened query 'Per CDM: Per sponsor review, please verify data and if appropriate, update "Date" for line 12 on Symptom Log, since it appears to be off sequence. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 00:18:34
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	28 Jan 2021 00:11:10
User entered '31 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	28 Jan 2021 00:10:48
User entered '31 Dec 2021'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.7' F	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.		28 Apr 2021 20:05:58
Data hard locked.		26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:10:48

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4)	
	Dhwani Shah (b) (4)	28 Jan 2021 00:11:10
	(b) (4)	

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 00:16:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 00:16:10
User entered '11 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 00:11:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '96' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:16:10
User entered empty.	System	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:16:10
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:16:10
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:11:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User closed query 'Per CDM: Per sponsor review, please verify data for there are 2 forms with Symptom Day recorded as 'Day 14'. Please consider this form to follow in sequence with this update, according to the dates reported, else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 03:08:45
Query 'Per CDM: Per sponsor review, please verify data for there are 2 forms with Symptom Day recorded as 'Day 14'. Please consider this form to follow in sequence with this update, according to the dates reported, else clarify.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	17 Mar 2021 22:40:51
User opened query 'Per CDM: Per sponsor review, please verify data for there are 2 forms with Symptom Day recorded as 'Day 14'. Please consider this form to follow in sequence with this update, according to the dates reported, else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 00:33:21
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 14 (Day 14)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '12 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '96'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97.9' F	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:09:20
User closed query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).		12 Feb 2021 17:09:18
Query 'Please confirm response. Per source, Mild is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	01 Feb 2021 17:56:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 17:55:58
User opened query 'Please confirm response. Per source, Mild is marked. Please update as applicable. (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:18:37
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 17:18:24
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:18:10

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 14 (Day 14)'	(b) (4) Dhwani Shah (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '13 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Moderate (Moderate)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4)	28 Jan 2021 00:20:02

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 15 (Day 15)'	(b) (4) Dhwani Shah (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '14 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F	Dhwani Shah (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:21:45

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 16 (Day 16)'	(b) (4) Dhwani Shah (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '15 Jan 2021'	Dhwani Shah (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F	Dhwani Shah (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:09:43
User closed query 'Please confirm response. Per source, None is marked. Please update as applicable. ' (Site from CRA).		12 Feb 2021 17:09:40
Query 'Please confirm response. Per source, None is marked. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:55:29
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:55:22
User opened query 'Please confirm response. Per source, None is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:21:54
Query 'Please confirm response. Per source, Mild is marked. Please update as applicable. ' canceled (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:21:41
User opened query 'Please confirm response. Per source, Mild is marked. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:21:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 17:21:20
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:23:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 17 (Day 17)'	(b) (4) Dhwani Shah (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '16 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '99'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98.6' F	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'Mild (Mild)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:25:15

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 18 (Day 18)'	(b) (4) Dhwani Shah (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 00:26:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 00:26:28
User entered '17 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 00:25:24
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:25:24

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:40:35
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Day 19 (Day 19)'	(b) (4) Dhwani Shah (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '18 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '98'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '%'	System	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered '97.1' F	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:56:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:05:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:55:43
User entered 'None (None)'	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:26:28

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered '31 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[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 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

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 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User closed query 'Per CDM: COVID-19 is not added to the AE form, Please review and update AE form accordingly.' (Site from DM).		12 Jan 2021 09:44:52
Query 'Per CDM: COVID-19 is not added to the AE form, Please review and update AE form accordingly.' answered with 'UPDATED AE' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:25:46
User opened query 'Per CDM: COVID-19 is not added to the AE form, Please review and update AE form accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 10:22:34
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 10:19:39
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 'UPDATED' (Site from System).	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:59
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 Jan 2021 15:57:53
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered '31 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered empty.	Dhwani Shah (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

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 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	07 Jan 2021 15:58:12
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	07 Jan 2021 15:57:53
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:44:16
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:58:12
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:56:17

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	07 Jan 2021 15:57:53

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

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 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:48:18
User closed query 'Please confirm response. Per symptom log, subject experienced a SpO2 rate of 92% on 08JAN2021. Please update as applicable and Please update this page as additional information becomes available. ' (Site from CRA).		26 Jan 2021 23:17:13
Query 'Please confirm response. Per symptom log, subject experienced a SpO2 rate of 92% on 08JAN2021. Please update as applicable and Please update this page as additional information becomes available. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 01:14:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 01:14:48
User opened query 'Please confirm response. Per symptom log, subject experienced a SpO2 rate of 92% on 08JAN2021. Please update as applicable and Please update this page as additional information becomes available. ' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 00:20:52
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered '08 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 01:14:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered '09 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 01:14:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered '92' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 01:14:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

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[End Date](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
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US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
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US3562015

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Folder: Covid-19 Assessment 30 Dec 2020

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US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
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User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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US3562015

Folder: Covid-19 Assessment 30 Dec 2020

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[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 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered 'No (N)'	Dhwani Shah (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:56:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:48:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:14:19

US3562015

Folder: Covid-19 Assessment 30 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:56:17

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:06:19
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:01:02
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:26:04

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 3 (Day 3)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 14:59:24
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:43:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F60AYE' (Site from DM).	Dhwani Shah (b) (4)	01 Feb 2021 14:19:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:21:20
User entered '02 Jan 2021'	Dhwani Shah (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 5 (Day 5)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. '(Site from DM).	(b) (4), (b) (6)	22 Feb 2021 14:59:29
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:43:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F63983' (Site from DM).	Dhwani Shah (b) (4)	01 Feb 2021 14:19:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. '(Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:21:28
User entered '04 Jan 2021'	Dhwani Shah (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 7 (Day 7)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:39:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 23:39:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 23:39:05
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 14:11:47
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. '(Site from DM).	(b) (4), (b) (6)	22 Feb 2021 14:59:34
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:43:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F63983' (Site from DM).	Dhwani Shah (b) (4)	01 Feb 2021 14:20:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. '(Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:21:36
User entered '6 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4)	11 Jan 2021 23:39:05
User entered empty.	Dhwani Shah (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 9 (Day 9)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:39:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 23:39:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 23:39:05
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 14:11:47
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered '8 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 23:39:05
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 14 (Day 14)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 23:39:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 23:39:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 23:39:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 14:11:47
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User closed query 'Per CDM: Was Saliva Collected?' is noted YES however Date of collection is missing. Please review and update accordingly. else clarify.' (Site from DM).		29 Jan 2021 16:39:37
Query 'Per CDM: Was Saliva Collected?' is noted YES however Date of collection is missing. Please review and update accordingly. else clarify.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 15:16:33
User entered '13 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 15:16:23
User opened query 'Per CDM: Was Saliva Collected?' is noted YES however Date of collection is missing. Please review and update accordingly. else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:37:17
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 21 (Day 21)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	29 Jan 2021 22:41:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 03:20:16
Query 'Data is required. Please complete.' answered with 'will update once collect' (Site from System).	Dhwani Shah (b) (4)	11 Jan 2021 23:40:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	11 Jan 2021 14:11:47
User entered empty.	Dhwani Shah (b) (4)	11 Jan 2021 14:11:47
	(b) (4)	

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered '20 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:41:26
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:56:17

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User accepted default value 'Day 28 (Day 28)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:56:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	29 Jan 2021 22:41:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 03:21:58
Query 'Data is required. Please complete.' answered with 'will update once collect' (Site from System).	Dhwani Shah (b) (4)	11 Jan 2021 23:40:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	11 Jan 2021 14:11:47
User entered empty.	Dhwani Shah (b) (4)	11 Jan 2021 14:11:47
	(b) (4)	

US3562015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:43:35
User entered '29 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:41:26
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:11:47

US3562015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:09
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:56:45

US3562015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:10
User entered '31 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:56:45

US3562015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:10:18
User closed query 'Please confirm response. Per source, Illness Visit Day 1 was done at the subject's home. Please update as applicable. ' (Site from CRA).		12 Feb 2021 17:10:15
Query 'Please confirm response. Per source, Illness Visit Day 1 was done at the subject's home. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:51:25
User entered 'Home (Home)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 17:51:19
User opened query 'Please confirm response. Per source, Illness Visit Day 1 was done at the subject's home. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 16:25:04
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:56:45

US3562015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'SICKD1'	System	07 Jan 2021 15:56:45

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered '31 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered '09:43'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '31 Dec 2020 09:43'	System	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	11 Jan 2021 14:10:58
DataPoint set to visible.	(b) (4) System	07 Jan 2021 15:56:45

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	11 Jan 2021 14:10:58
DataPoint set to visible.	(b) (4) System	07 Jan 2021 15:56:45

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered '98.7' F	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per ETRTR: Please confirm clinical significance and consider AE reporting, thanks.' (Site from CRA).	(b) (4)	12 Feb 2021 17:10:34
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:25:59
Query 'Per ETRTR: Please confirm clinical significance and consider AE reporting, thanks.' answered with 'confirmed NCS' (Site from CRA).	Dhwani Shah (b) (4)	31 Jan 2021 18:25:48
User opened query 'Per ETRTR: Please confirm clinical significance and consider AE reporting, thanks.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:00:55
User entered '100'	Dhwani Shah (b) (4)	11 Jan 2021 14:10:58
	(b) (4)	

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'bpm'	System	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered '16'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'breaths/min'	System	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered '144'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:25:59
User entered '88'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	11 Jan 2021 14:10:58

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:26:56
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:56:56

US3562015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:26:56
User entered '31 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:56:56

US3562015

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:56:17

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:28:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:07

US3562015

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:28:45
User entered '31 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	07 Jan 2021 15:57:07

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:31:57
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:37:57

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:31:57
User entered '29 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:37:57

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:31:57
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:37:57

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'SICKD28'	System	29 Jan 2021 22:37:57

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '29 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '13:31'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '29 Jan 2021 13:31'	System	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '71.2' in	Dhwani Shah (b) (4)	29 Jan 2021 22:38:33
DataPoint set to visible.	(b) (4) System	29 Jan 2021 22:37:57

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '247' lb	Dhwani Shah (b) (4)	29 Jan 2021 22:38:33
DataPoint set to visible.	(b) (4) System	29 Jan 2021 22:37:57

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '97.8' F	Dhwani Shah (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered empty.	Dhwani Shah (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '97'	Dhwani Shah (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'bpm'	System	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '16'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'breaths/min'	System	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:32:37
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'CONFIRMED NCS' (Site from DM).	Dhwani Shah (b) (4)	05 Feb 2021 17:28:28
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:20:54
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '163'	Dhwani Shah (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:05
User entered '84'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'mmHg'	System	29 Jan 2021 22:38:33

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:56:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:51

US3562015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:56:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:18
User entered '29 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:51

US3562015

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:56:17

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:27
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:58

US3562015

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:56:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:27
User entered '29 Jan 2021'	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 22:38:58

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:25:46

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '15 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:25:46

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:25:46

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:56:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'UNBLND_DECIDE'	System	08 Mar 2021 15:25:46

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '15 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Dhwani Shah (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '15 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Placebo (Placebo)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Placebo (Placebo)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Placebo (Placebo)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 15:03:33
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	08 Mar 2021 15:27:21
	(b) (4)	

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:56:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	24 Mar 2021 15:03:33
User entered 'I'	System	08 Mar 2021 15:27:21

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:26:40

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '15 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:26:40

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '13:53'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:26:40

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '15 Feb 2021 13:53'	System	08 Mar 2021 15:26:40

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:56:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:26:59

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:56:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '15 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:26:59

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:56:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '13:55'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Mar 2021 15:26:59

US3562015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '15 Feb 2021 13:55'	System	08 Mar 2021 15:26:59

US3562015

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:56:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:34:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:12:07
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	28 Aug 2020 00:17:08

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
Reviewed for Safety.		11 Jan 2021 19:33:04
User entered 'USA-US071-2021-mRNA-1273-P301000002'	System	11 Jan 2021 19:33:00
User entered 'New'	(b) (4), (b) (6)	11 Jan 2021 19:33:00

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 14:14:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 14:14:05
Data point term sent to Coder	System	11 Jan 2021 14:13:33
User entered 'COVID 19 INFECTION'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Please confirm if this response should be YES as subject was seen for Illness Visit and is being followed in the 28 Day Convalescent Period. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:04:39
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:35:02
Query 'Please confirm if this response should be YES as subject was seen for Illness Visit and is being followed in the 28 Day Convalescent Period. Please update as applicable. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	28 Jan 2021 00:27:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 00:27:31
User opened query 'Please confirm if this response should be YES as subject was seen for Illness Visit and is being followed in the 28 Day Convalescent Period. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 18:47:28
User entered 'No (N)'	Dhwani Shah (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '30 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:27:31
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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). DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:09:59
	(b) (4), (b) (6)	01 Feb 2021 17:35:02
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)	28 Jan 2021 00:27:43
User entered '18 Jan 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:27:31
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)	20 Jan 2021 19:19:48
User entered empty.	Dhwani Shah (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:39:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'Not Applicable (NOT APPLICABLE)'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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) (4), (b) (6)	03 Feb 2021 19:10:03
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:35:02
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UPDATED CONMED ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:28:16
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)	20 Jan 2021 19:20:10
User entered 'I'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:35:02
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPDATED' (Site from Safety).	Dhwani Shah (b) (4)	28 Jan 2021 00:27:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:27:31
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 19:20:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User closed query 'PV Query: On 08 Jan 2021, O2 saturation was 92% on symptom log but narrative details show 93%. Please review data and reconcile accordingly. However, if it is correct as reported, please clarify.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:33:38
User closed query 'PV Query: Please provide results of chest x-ray and echocardiogram.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:33:30
Query 'PV Query: Please provide results of chest x-ray and echocardiogram.' answered with 'x-ray and echocardiogram results are unknown, site did not receive it' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	10 Mar 2021 17:50:10
Query 'PV Query: On 08 Jan 2021, O2 saturation was 92% on symptom log but narrative details show 93%. Please review data and reconcile accordingly. However, if it is correct as reported, please clarify.' answered with 'pt reported 92% during telehealth but when pt went to ER it was 93% per medical records' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	10 Mar 2021 17:47:17
User opened query 'PV Query: On 08 Jan 2021, O2 saturation was 92% on symptom log but narrative details show 93%. Please review data and reconcile accordingly. However, if it is correct as reported, please clarify.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:54:45
User opened query 'PV Query: Please provide results of chest x-ray and echocardiogram.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:54:31
User closed query 'Per DM CLR: Narrative = DONE CHEST XRAY AND ECHOCARDIOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:29:49

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = DONE CHEST XRAY AND ECOCARDIOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Please note xray and ecocardiogram is not a procedure or surgery and does not need to entered under concomitant procedure ' (Site from DM).	Dhwani Shah (b) (4)	22 Feb 2021 23:58:52
User opened query 'Per DM CLR: Narrative = DONE CHEST XRAY AND ECOCARDIOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:40:56
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:35:02
User entered 'PT WENT TO ER ON 1/8/21 TO EVALUTION OF SHORTNESS OF BREATH, OXIMETER HAS BEEN READING 93%, DONE CHEST XRAY AND ECOCARDIOGRAM AT ER , PT WAS DISCHARGE WITHIN FEW HOURS' reason for change: Data Entry Error	Dhwani Shah (b) (4)	28 Jan 2021 00:39:19
User entered empty.	Dhwani Shah (b) (4)	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '0'	System	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '1'	System	28 Jan 2021 00:27:31
User entered '0'	System	11 Jan 2021 14:13:18

US3562015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:56:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:56:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per ETRTR: According to COVID-19 AE page, Concomitant Medications were dosed. Please add medication dosing details for COVID-19, otherwise reconcile data within AE page, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:05:09
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:35:14
Query 'Per ETRTR: According to COVID-19 AE page, Concomitant Medications were dosed. Please add medication dosing details for COVID-19, otherwise reconcile data within AE page, thanks.' answered with 'please rereview it has been already added back on conmed page for covid 19 medication ' (Site from CRA).	Dhwani Shah (b) (4)	28 Jan 2021 21:16:17
User opened query 'Per ETRTR: According to COVID-19 AE page, Concomitant Medications were dosed. Please add medication dosing details for COVID-19, otherwise reconcile data within AE page, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:59:44
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	14 Aug 2020 14:55:54

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 18:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 18:35:25
Data point term sent to Coder	System	14 Aug 2020 14:57:13
User entered 'Metformin hydrochloride'	Dhwani Shah (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'diabetes type II'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '1000'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'twice daily (BID)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:11:52
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 14:57:03
User entered 'un UNK 2011'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2'	System	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 14:57:03

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:00:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:00:22
Data point term sent to Coder	System	14 Aug 2020 14:59:19
User entered 'Atorvastatin calcium'	Dhwani Shah (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:06:09
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	22 Oct 2020 22:54:48
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 19:00:03
User entered 'hyperlipidemia'	Dhwani Shah (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '10'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:11:57
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 14:58:56
User entered 'un UNK 2014'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 14:58:56

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 15:02:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Aug 2020 15:02:17
Data point term sent to Coder	System	14 Aug 2020 15:01:21
User entered 'tamsulosin'	Dhwani Shah (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Enlarged prostate'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0.4'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:12:00
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 15:00:31
User entered 'un UNK 2014'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 15:00:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 15:03:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:03:18
Data point term sent to Coder	System	14 Aug 2020 15:02:22
User entered 'Aripiprazole'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Depression'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '5'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:12:04
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 15:01:31
User entered 'un UNK 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:01:37
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:01:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:01:31
	Dhwani Shah (b) (4)	14 Aug 2020 15:01:31
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 15:01:31

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: SERTRALINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:46:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:46:23
Data point term sent to Coder	System	14 Aug 2020 15:45:02
Data point term sent to Coder	System	14 Aug 2020 15:43:59
User entered 'sertraline HCL'	Dhwani Shah (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:44:17
User entered 'Depression' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:44:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:43:23
	Dhwani Shah (b) (4)	14 Aug 2020 15:43:23
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '25'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:12:07
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 15:43:23
User entered 'un UNK 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:44:17
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:44:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:43:23
	Dhwani Shah (b) (4)	14 Aug 2020 15:43:23
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 15:43:23

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: LINAGLIPTIN, PRODUCTSYNONYM: TRADJENTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:48:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:48:18
Data point term sent to Coder	System	14 Aug 2020 15:47:09
Data point term sent to Coder	System	14 Aug 2020 15:46:08
User entered 'Tradjenta'	Dhwani Shah (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:46:49
User entered 'Diabetes Type II' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:46:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:45:32
	Dhwani Shah (b) (4)	14 Aug 2020 15:45:32
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '5'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:12:12
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 15:45:32
User entered 'un UNK 2014'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:46:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:46:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:45:32
	Dhwani Shah (b) (4)	14 Aug 2020 15:45:32
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 15:45:32

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 15:49:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:49:17
Data point term sent to Coder	System	14 Aug 2020 15:48:10
User entered 'loratadine'	Dhwani Shah (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:47:56
User entered 'Seasonal allergies' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:47:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:47:43
	Dhwani Shah (b) (4)	14 Aug 2020 15:47:43
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '10'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:12:16
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 15:47:43
User entered 'un UNK 2020'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'l'	System	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 15:47:43

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 23:02:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 23:02:20
Data point term sent to Coder	System	22 Oct 2020 23:01:10
Coding entries removed.	Dhwani Shah (b) (4)	22 Oct 2020 23:00:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Aug 2020 15:52:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Aug 2020 15:52:22
Data point term sent to Coder	System	14 Aug 2020 15:51:21
Data point term sent to Coder	System	14 Aug 2020 15:50:15
User entered 'Fluticasone propionate'	Dhwani Shah (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 15:50:31
User entered 'Seasonal allergies' reason for change: Data Entry Error	Dhwani Shah (b) (4)	14 Aug 2020 15:50:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 15:49:37
	Dhwani Shah (b) (4)	14 Aug 2020 15:49:37
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '50'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'ug (ug)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User closed query 'For reconciliation purposes: Please review route, as this is not the expected route for this medication. Please review if Route could be appropriately reported using one of available options (e.g. Nasal) . Please review and correct as appropriate or confirm otherwise . ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:17:40
Query 'For reconciliation purposes: Please review route, as this is not the expected route for this medication. Please review if Route could be appropriately reported using one of available options (e.g. Nasal) . Please review and correct as appropriate or confirm otherwise . ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	22 Oct 2020 23:00:41
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 23:00:20
User opened query 'For reconciliation purposes: Please review route, as this is not the expected route for this medication. Please review if Route could be appropriately reported using one of available options (e.g. Nasal) . Please review and correct as appropriate or confirm otherwise . ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 19:00:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Dhwani Shah (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
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)	14 Aug 2020 22:12:20
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 15:49:37
User entered 'un UNK 2016'	Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	14 Aug 2020 15:49:37

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 00:24:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 00:24:20
Data point term sent to Coder	System	14 Aug 2020 15:54:30
User entered 'humalog'	Dhwani Shah (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Diabetes Type II'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '4'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mL (mL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'twice daily (BID)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'UN Jan 2020' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	08 Sep 2020 23:14:31
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) (4), (b) (6)	14 Aug 2020 22:12:27
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 15:54:18
User entered 'un UNK 2020'	Dhwani Shah (b) (4)	14 Aug 2020 15:54:18
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '2'	System	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	14 Aug 2020 15:54:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: BASAGLAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 05:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 05:33:33
Data point term sent to Coder	System	08 Sep 2020 23:14:55
User entered 'BASAGLAR KWIPEN'	Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'DIABETES TYPE II'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '20'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mL (mL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'UN Feb 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	08 Sep 2020 23:14:18

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: TOUJEO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 23:18:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:18:58
Data point term sent to Coder	System	08 Sep 2020 23:18:01
User entered 'TOUJEO'	Dhwani Shah (b) (4)	08 Sep 2020 23:17:21
	(b) (4)	

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'DIABETES TYPE II'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '20'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mL (mL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'UN Feb 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered 'I'	System	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '804 (804)'	System	08 Sep 2020 23:17:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC-D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 13:35:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 13:35:19
Data point term sent to Coder	System	28 Jan 2021 00:29:35
User entered 'ZYRTEC D'	Dhwani Shah (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'COVID 19 INFECTION'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'tablet (TABLET)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '07 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '17 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:29:28

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:50:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:50:17
Data point term sent to Coder	System	28 Jan 2021 00:40:41
User entered 'MOTRIN'	Dhwani Shah (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'COVID 19 INFECTION'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '600'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '08 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '08 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:40:20

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 00:42:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 00:42:10
Data point term sent to Coder	System	28 Jan 2021 00:41:42
User entered 'TYLENOL'	Dhwani Shah (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'COVID 19 INFECTION'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '1000'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '08 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '08 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:40:59

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: OTHER ANTIVIRALS, PRODUCT: OTHER ANTIVIRALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:31:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:31:32
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: MONOCLONAL ANTIBODIES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 11:54:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 11:54:16
Data point term sent to Coder	System	28 Jan 2021 00:42:43
User entered 'BAMlanivimab'	Dhwani Shah (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'covid 19 infection'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '700/20'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Other (OTHER)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'mg/ml'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'once (ONCE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '08 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '08 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:56:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered empty.	System	28 Jan 2021 00:42:21

US3562015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:56:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Sep 2020 00:52:55

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '23 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

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)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'Sponsor decided last dose for study vaccine March 25th2021 and pt received monoconol anitbodies and not eligible to received vaccine till Apr9th2021. Pt withdrew consent'	(b) (4) Dhwani Shah (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

If reason for discontinuation is [Death](#), main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:56:17

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	24 Mar 2021 15:06:06

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'USA-US071-2021-MRNA-1273-P301000002'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'Joseph'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Davis'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered '3900 E Camel Back road'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Phoenix'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered '85018'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:10:14
DataPoint Verified.		01 Feb 2021 17:33:55
User entered 'US'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '3'	System	11 Mar 2021 21:37:03
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered '2'	System	03 Feb 2021 19:10:22
User entered '1'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'USA-US071-2021-MRNA-1273-P301000002'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Joseph'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'Davis'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered '3900 E Camel Back road'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Phoenix'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered '85018'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:10:14
DataPoint Verified.		01 Feb 2021 17:33:55
User entered 'US'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '3'	System	11 Mar 2021 21:37:03
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered '2'	System	03 Feb 2021 19:10:22
User entered '1'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:56:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
User entered '11/Jan/2021 14:33'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:56:17

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:10:14
DataPoint Verified.		01 Feb 2021 17:33:55
User entered 'I'		11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'USA-US071-2021-MRNA-1273-P301000002'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'Joseph'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Davis'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered '3900 E Camel Back road'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Phoenix'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered '85018'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:10:14
DataPoint Verified.		01 Feb 2021 17:33:55
User entered 'US'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '3'	System	11 Mar 2021 21:37:03
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered '2'	System	03 Feb 2021 19:10:22
User entered '1'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:56:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:33:48
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered '03/Feb/2021 14:10'	(b) (4) System	03 Feb 2021 19:10:22

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:56:17

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:33:50
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 21:36:40
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 19:10:22

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'USA-US071-2021-MRNA-1273-P301000002'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'No (N)'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Joseph'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Davis'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.		11 Jan 2021 19:33:16
User entered '3900 E Camel Back road'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered 'Phoenix'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 17:33:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 19:33:16
User entered '85018'	System	11 Jan 2021 19:33:00

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:10:14
DataPoint Verified.		01 Feb 2021 17:33:55
User entered 'US'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:56:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
User entered '3'	System	11 Mar 2021 21:37:03
User signature succeeded.	Joseph Davis (b) (4)	17 Feb 2021 20:59:44
	(b) (4)	
User entered '2'	System	03 Feb 2021 19:10:22
User entered '1'	System	11 Jan 2021 19:33:21

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:56:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:07
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered '11/Mar/2021 16:37'	(b) (4) System	11 Mar 2021 21:37:03

US3562015

Folder: SAE USA-US071-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:56:17

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:22:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:34:09
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:35:58
User entered 'l'	(b) (4), (b) (6)	11 Mar 2021 21:37:03